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**Understanding Society Wave 16 pilot: Biomarker data
collection in the UK Household Longitudinal Study**

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Non-technical summary

Understanding Society: the UK Household Longitudinal Study (UKHLS) is a longitudinal social survey of households and individuals living in the UK. The overall purpose of *Understanding Society* is to provide high quality longitudinal data about subjects such as health, work, education, income, family, and social life.

In the second and third waves of the study (2010-12) a wide range of objective health measures were collected, which have been extensively used by the public health and social science research communities. This data collection will be greatly enhanced by a re-collection of biomarker data to enable researchers to examine changes in them over time. However, repeat collection of biomarker data in *Understanding Society* using nurses is no longer feasible.

At Wave 16 of *Understanding Society* (2024-2026) we propose to collect a range of biomarkers measured by participants themselves. Prior to that fieldwork, we are piloting the data collection processes during February-May 2023. This paper sets out the design of the Wave 16 pilot.

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Abstract: Biomarkers have been included in several major longitudinal surveys, including Understanding Society in Waves 2 and 3 (2010-2012). This data collection will be greatly enhanced by a re-collection of biomarker data to enable researchers to examine changes in them over time. However, repeat collection of biomarker data in Understanding Society using nurses is no longer feasible. At Wave 16 of Understanding Society (2024-2026) we propose to collect a range of biomarkers directly from participants. Prior to that fieldwork, we are piloting the data collection processes during February-May 2023. This paper sets out the design of the Wave 16 pilot.

Keywords: biomarkers, longitudinal, survey, blood sample, microbiome.

JEL classification: C83, C93.

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Understanding Society Wave 16 pilot: Biomarker data collection in the UK Household Longitudinal Study

1. BACKGROUND

Understanding Society: the UK Household Longitudinal Study (UKHLS) is a longitudinal social survey of households and individuals living in the UK (Buck and McFall, 2011). Data collection began in January 2009 and participants are interviewed annually. In the second and third waves (2010-12) a wide range of objective health measures were collected, which have been extensively used by the public health and social science research communities. We plan to conduct another wave of bio-data collection at Wave 16 (2024-26). The survey is designed and managed by the Institute for Social and Economic Research (ISER) at the University of Essex. Pseudo-anonymised data for statistical analysis are made available to the research community for analysis via the UK Data Service (UKDS). Genetics and epigenetics data alone are available from [European Genome-phenome Archive](#) (EGA) and in combination with survey data by [application form](#) from the Study team.

The overall purpose of *Understanding Society* is to provide high quality longitudinal data about subjects such as health, work, education, income, family, and social life. Its design is based on the long-running British Household Panel Survey (BHPS), carried out since 1991 by ISER, and whose sample was incorporated into *Understanding Society* at Wave 2 (2010). The Study provides information to help understand the long-term effects of social and economic change, as well as gauge the success of policy interventions designed to impact upon the general health, social and economic well-being of the UK population.

This paper provides an overview of *Understanding Society* and detailed information about the Wave 16 pilot, to take place in early 2023. Building on learning from this pilot, we will review the design for the full Wave 16 fieldwork.

2. RATIONALE

Biomarkers have been included in several major longitudinal surveys, including the MRC National Survey of Health and Development Cohort/1946 Birth Study (Wadsworth et al, 2006), 1958 National Child Development Study (Power and Elliot, 2005) and the English Longitudinal Study of Ageing/ELSA (Stephoe et al, 2013) as a way of allowing researchers to investigate how people's social and economic lives interact with their biology and health outcomes over time.

Biomarker data have also been collected by nurses from participants of *Understanding Society* in Waves 2 and 3 (2010-2012) (McFall et al, 2012; Benzeval et al, 2014). These data have enabled significant advances in social-biological research in high impact biology, medicine, public health, social sciences, statistics, and interdisciplinary journals.¹ This data collection would be greatly enhanced by a re-collection of biomarker data to enable researchers to examine changes in them over time. However, repeat collection of biomarker data in *Understanding Society* using a nurse has become difficult for two reasons. Firstly, nurse-administered data collection on a population sample the size of *Understanding Society* is prohibitively expensive and, secondly, there has been a move away from face-to-face data collection to web-based data collection in the Study. This results in the need to use alternative methods to collect biomarker data from participants, such that data are comparable to those collected in earlier waves of the Study but also remain novel and at the forefront of biosocial research (Kumari and Benzeval, 2021). We tested alternative methods to collect biomarker data in IP12 (Al Baghal et al 2021) and based on that experience we are planning to collect biomarkers on the main population sample at Wave 16 (2024-2026). This data collection will be preceded by a pilot of the fieldwork processes, to be carried out in early 2023.

Understanding Society uses a mixed-mode design, in which the majority of participants are invited to complete their interview online, and the remaining sample members are issued to interviewers. In both modes, if participants do not respond in their issued mode, after a number of reminders over time (details below), they are invited to participate in the other mode. In the pilot, participants will be randomly allocated to two groups: (i) "participant-led" where participants are invited to

¹ see <https://www.understandingsociety.ac.uk/research/publications/subject/Biology>

complete an online survey with self-measured and reported biomeasures and self-collection of biological samples (60% of the sample); and (ii) “interviewer-led” with an interviewer collecting survey data, and biomeasures, with self-collection of biological samples (40% of the sample). Across each group we plan to collect anthropometric measures (height, weight, hip and waist circumference), blood pressure and biological samples (a capillary blood sample from all participants and a stool sample from a random subset). Collection of the blood sample would enable measurement of analytes that overlap with those collected at Waves 2 and 3 of the main-stage and at IP12, as well as additional measures key to current public health priorities. Novel measurements from stool samples will provide insights into new biological pathways that mediate health inequalities currently not possible from blood and other tissues.

3. RESEARCH QUESTION/AIMS

Collecting biomarkers again at Wave 16 on all adult members of households for a general population sample would create significant new and unique scientific opportunities for a wide range of researchers worldwide. Although this paper covers the protocol of the Wave 16 pilot, the pilot was designed to make sure that the main Wave 16 data collection will be able to provide data so that researchers can address important research questions. We have four aims for this data collection (Kumari et al, 2022), to:

1. Understand the biological pathways that connect society and health:

- The social environment and health interact in a bi-directional manner over time such that both can be explanatory factors for outcomes in the other. Social science and health researchers need extensive, high-quality data on both the environment and biology to best understand these associations. Such evidence can inform broad strategies to improve public health and reduce health inequalities as well as promote and maintain a productive workforce.
- *Understanding Society* captures detailed information about the social environment and health, including biomarkers, across the lifespan and intergenerationally within families. The longitudinal core includes annual collection of extensive data on multiple facets of life with additional data provided through a number of administrative record

linkages. Biomarker data was also previously collected at Waves 2/3. The biomarkers collected at Wave 16 will provide indicators of a variety of important health outcomes that may be influenced by people's preceding social environment and/or influence their subsequent social trajectories and health. Biomarker and social data will be useful for both cross-sectional and longitudinal analyses.

2. Measure the prevalence of undiagnosed conditions/sub-clinical measures in different social groups:

- The extent of health conditions in the population is not fully identified because in many instances conditions are undiagnosed and/or people are unaware of their symptoms. More research is needed about the extent of these health conditions (at any stage of diagnosis) for different parts of the population and across the entire lifespan in order to design effective prevention and early detection strategies. Understanding the groups that are more likely to have undiagnosed conditions, and the factors associated with this, will enable the targeting of prevention policies and understand future health service needs.
- *Understanding Society* will contribute by including biomarkers that indicate health conditions and can identify the prevalence of diseases, including undiagnosed/untreated or poorly controlled cases, in a large representative sample. *Understanding Society* includes participants in sizable numbers from a variety of subgroups across all life stages with a longitudinal design capturing ageing. The nature of this sample allows for studies of prevalence of disease in sub groups of the population not frequently studied, how prevalence changes as people age and over time and track and compare longer term social and health outcomes by diagnosis or treatment status.

3. Enable the health impacts associated with macro-change in society to be investigated:

- Society is constantly changing, including unforeseen events, which can have a direct impact on changes in living conditions and health. By capturing the social environment and health of individuals before,

during and after these changes emerge, researchers can establish the pathways that societal developments can have on biology.

- The longitudinal design and the large representative sample of the UK makes *Understanding Society* the best placed study to capture the immediate and long term impacts of these societal changes on health through the inclusion of biomarkers to the already collected and extensive social survey data. Capturing a multitude of biomarkers longitudinally, *Understanding Society* enables population-level inferences of the impact of societal changes on health outcomes and health service needs. Having before and after indicators through the longitudinal design allow for stronger claims of causality.

4. Provide national representative benchmark of key biomarker measures:

- The provision of data that is used as a benchmark for similar biomarkers collected in other studies or clinical settings helps contextualise smaller specialised studies, and promotes the uptake in usage of biomarkers. The benefits of benchmarking are only possible because *Understanding Society* is representative of the whole population.
- The national and representative nature of *Understanding Society* enables it to be positioned as a benchmark for biomedical studies or routinely-held clinical data, and there is precedence for it being used in this way. The extensive nature of the data includes measurements of risk factors for disease which provides population-level understanding of these biomarkers. *Understanding Society* also is at the forefront of setting these benchmarks for emergent measures as it incorporates new biomarkers as the study progresses. This includes newer measures such as polygenic scores or from the microbiome.

The aim of the Wave 16 pilot is to test that the design of the biomarker collection wave is effective across the different mode groups, and we have effective process in place to ensure measurements are requested if participants switch mode. The pilot tests the proposed fieldwork design for Wave 16, including the acceptability of biomeasures and the request for tissue samples. The pilot will also examine the willingness to receive the kit to collect microbiome and blood samples, and the

compliance with the collection and return protocols. Participants will be asked to report on their reasons for not participating, if appropriate, and how the Study can be improved to inform the main fieldwork. Interviewers will be asked to complete a feedback form and report their experiences carrying out the survey and the various biomeasures. Interviewers will also be invited to attend a debrief at the end of the pilot fieldwork period. The analysis of the pilot will include the effectiveness of the data flows between ISER and the fieldwork agency; the fieldwork agency and the laboratory responsible for blood analysis; the fieldwork agency and the participants; and the participants and the University of Essex. These data flows include the effectiveness of communicating results to participants. The results of the pilot will feed into finalising the design for Wave 16.

4. STUDY DETAILS

Understanding Society is a longitudinal study. Participants in the *Understanding Society* sample have already been recruited and have been interviewed at least once before. To be included in Wave 16 of *Understanding Society*, a person must be part of a household that has taken part in one or more previous surveys as part of *Understanding Society*, and reside in the UK. This does mean that some participants will be interviewed for the first time in this wave, for example, if they join a previously participating household through a new cohabitation or marriage.

To be included in the Wave 16 pilot, a person must be part of a household that has participated in one or more previous surveys as part of the *Understanding Society* pilot, and reside in England or Scotland, and be able to respond to the survey in English. More detailed inclusion and exclusion criteria are given in Section 8.2, below.

The Wave 16 sample will be purposively allocated into one of two groups, based on the characteristics and previous participation of the household members: 1) 60% into the participant-led web mode, and 2) 40% into the interviewer-led mode. Group selection will be done at household level (all participants in a household will be allocated to the same mode). Following our standard protocols, if a participant does not complete in their invitation mode, they will be offered other modes later in the

fieldwork process. The overall study design for the Wave 16 has been summarised below, in Table 1, which provides details of the specific measures in each group and indicates the sections of the protocol where they are described in detail. For the pilot of Wave 16, the sample will be randomly split into the two groups.

Table 1: Measures collected from adult participants

ADULT PARTICIPANTS (AGED 16 YEARS AND OVER)			Section of paper
	WEB-MODE (n*= 220) *number of estimated issued adults in the pilot	INTERVIEWER MODE (n*= 150) *number of estimated issued adults in the pilot	
1. Questionnaire	Participant-led Online survey <i>Token of appreciation: Same as current main-stage (£20)</i>	Interviewer-led CAPI (with self-completion section) <i>Token of appreciation: Same as current main-stage (£20)</i>	4.2.1 – 4.2.3
2. Cognitive measures	n/a	Interviewer-led CAPI (sub-sample)	4.2.4
3. Blood pressure	Blood pressure self-measurement before interview.	Blood pressure measurement taken by interviewer during interview – with consent	4.3.1
4. Anthropometric measures	Waist and hip circumference, self-measured before interview. Invitation to download Body Volume Index App to scan body and provide body measurements.	Waist and hip circumference self-measured during interview, supervised by interviewer. Height and weight measured by interviewer – with consent Invitation to download Body Volume Index App to scan body and provide body measurements.	4.3.2 – 4.3.4

5. Blood sample	Capillary blood sample kit sent to participant – with consent. <i>Token of appreciation: £5 conditional on returning sample.</i>	Capillary blood sample kit sent to participant – with consent. <i>Token of appreciation: £5 conditional on returning sample.</i>	4.4.1 – 4.4.2
6. Microbiome sample (for random subset of each group)	Microbiome kit sent to participant – with consent. <i>Token of appreciation: £5 conditional on returning sample.</i>	Microbiome kit sent to participant – with consent. <i>Token of appreciation: £5 conditional on returning sample.</i>	4.4.3

Group 1: Participant-led online mode

Participants (aged 16 years and over) will be invited to complete the questionnaire online. In the advance letter they will have been asked to measure their blood pressure and their hip and waist circumference and to record them on the card sent with the advance letter (See sections 4.3.1 and 4.3.3 below).

Group 2: Interviewer-led mode

Participants (aged 16 years and over) will first have a face-to-face interview with an interviewer using CAPI (Computer-assisted personal interviewing).

4.1 Contacting participants

Advance Letters/emails

Adult sample members will be sent an advance letter inviting them to participate in the interview. The letter will include an information leaflet on health measures collected in the Study. Adult sample members in the participant-led online mode for whom we have an email address will also receive an email invitation to the study. The email will include a link to the survey, and will include links to the information leaflet. Sample members have the opportunity to request further information or to opt out the survey at this point.

Those in the participant-led online mode will also be sent reminders if they do not complete online. These consist of an email/SMS/letter reminder sent after one week; a second email reminder after two weeks; and a third email/second letter reminder after three weeks. This is the standard protocol used on *Understanding Society*. In the pilot, after four weeks adult sample members in the online mode who have not completed their survey online are allocated to interviewers. For the main Wave 16 data collection, there would be the standard five weeks and there would be an additional email reminder after four weeks.

Adult sample members in the Interviewer-led group, and those who had not responded online after four weeks in the participant-led online group, are issued to interviewers. The interviewers will then try to contact the sample members by telephone, where possible, to arrange an appointment date and time for the face-to-face interview. After five weeks of interviewers working on the sample, those in the interviewer-led group who have not yet taken part in the survey will be invited to complete their interview online. Two weeks after this point, for one week interviewers will once again try to contact by telephone those adults who have not yet taken part, to see if they are willing to complete their interview by telephone. Fieldwork for the pilot finishes after three months. This is shorter than the fieldwork period planned for the main Wave 16 data collection, which will be around 4.5 months.

Sample members may seek further information or refuse involvement when the interviewer calls to make an appointment, when the interviewer visits and at any point during the administration of any of the components of the study. The advance letter will also contain contact details (Freephone, Freepost, email, website) that participants can use to contact *Understanding Society* to request more information, refuse this specific interview or to withdraw from the survey. In addition, the participant information leaflet contains information for the University of Essex's research office for participants who have concerns about the Study. As standard, the advance letter will also include a change-of-address slip section that the sample member can complete and return to inform the University of a change of address. A Freepost envelope is included in the pack to allow the sample member to return the slip.

4.2 Interview

The Understanding Society interview is split across three main instruments: the household enumeration; the household questionnaire; and then the individual adult questionnaire for those aged 16 and over. In the main Wave 16 data collection there will also be a youth self-completion for those aged 10-15. The pilot will not include the youth self-completion.

4.2.1 Household enumeration (5 minutes)

The first task within each household is to enumerate who is currently living in the household. The enumeration can be done by any adult in the household (aged 16+) and takes around 5 minutes. The participant is given a list of the people who were in the household at the previous interview and indicates whether they are still resident in the household. Basic information about anyone who has moved into the household and about those who have moved out of the household is collected.

4.2.2 Household questionnaire (10-15 minutes)

The household information questionnaire is completed by one adult on behalf of the whole household. This adult is the person in the household who is responsible for paying bills, or their spouse/partner. The questionnaire collects information on the house, household resources, and bills etc.

4.2.3 Adult questionnaire (45-80 minutes)

Each adult in the household is invited to complete their own individual interview. The standard interview takes around 45 minutes, depending on their circumstances. In addition, for those interviewed in-person with an interviewer would have around 20 minutes of physical measures. There are also 15 minutes of questions to measure cognitive function for a sub-sample of those interviewed face-to-face.

Understanding Society is a multi-topic survey. Major content areas include:

1. Demographics
2. Device and online activity
3. Initial conditions
4. Own first job

5. Educational aspirations
6. Young adults
7. Family background
8. Ethnicity and national identity
9. Religion
10. Disability
11. Self-measured blood pressure
12. Self-measured waist/hip
13. Health conditions
14. Health service use
15. BVI App introduction
16. Smoking
17. Nutrition
18. Exercise
19. Caring
20. Social care
21. Partnership history
22. Current pregnancies
23. Annual fertility history
24. Annual residential history
25. Annual education history
26. Annual employment history
27. Employment
28. Commuting behaviour
29. Job satisfaction
30. Work conditions
31. Physical work
32. Work illness
33. Parents return to work
34. Childcare
35. Cognition
36. Blood pressure
37. Height/weight
38. Waist/hip

- 39. Household Finances
- 40. Student loans
- 41. Self-completion health and well-being
- 42. Self-completion social support
- 43. Self-completion alcohol consumption
- 44. Self-completion young adults
- 45. Self-completion non co-resident relationships
- 46. Self-completion child development/parenting styles
- 47. Self-completion work conditions
- 48. Self-completion elections
- 49. Blood sample kit consent
- 50. Microbiome sample kit consent
- 51. Survey doctor
- 52. Contact details

In the pilot, at the start of the adult interview, participants who are interviewed by an interviewer will be asked for their verbal permission to audio record sections of the interview. These sections are:

- 1. Interviewer supervised waist and hip measurements
- 2. Blood sample kit consent
- 3. Microbiome sample kit consent

Face-to-face interviews will be conducted using computer-aided personal interviews (CAPI) in participants' homes.

4.2.4 Cognitive measures

At Wave 3 of *Understanding Society*, participants were asked a set of cognitive function measures. On the main Wave 16 survey, those participants who are still part of *Understanding Society* will be asked the same set of measures during their interview. In the pilot, a random half of adults issued to face-to-face interviewers will be asked to complete the same set of cognitive function measures.

In the main Wave 16 survey, but not the pilot, the remaining sample members will be asked a new set of measures online, either as part of their online interview, or as a separate online interview to which they will be invited two-to-three weeks after the completion of their annual interview. Sample members will be offered a £5 gift-card for completing the cognition survey. When invited to take part in the online cognitive survey after the annual interview, the invitation will be sent by letter with the URL of the online cognition survey and a unique access code. Where we have an email address for the sample member, we will send an email with a direct link to their cognition survey.

To summarise, the individual interview lengths are estimated to be:

- Interviewer-led mode, allocated to the Wave 3 cognitive measures:
 - 45 minute standard interview
 - 20 minute physical measures
 - 15 minute cognitive measures
- Interviewer-led mode, not allocated to the Wave 3 cognitive measures:
 - 45 minute standard interview
 - 20 minute physical measures
- Participant-led web mode:
 - 45 minute standard interview

Table 2 below summarises the sample for the cognitive measures at Wave 16.

Table 2: Summary of cognitive measures

Interviewer-administered groups:	Design	Content
Allocated to the Wave 3 cognitive measures	Asked Wave 3 measures as part of face-to-face interview	immediate and delayed word recall, serial 7 subtraction, number series, verbal fluency, and numeric ability

The cognitive measures carried at Wave 3 of Understanding Society are documented [online](#).² They include immediate and delayed word recall; serial 7 subtraction; number series; verbal fluency; and numeric ability.

4.3 Collection of biomeasures

We describe the protocol for each measure below, while exclusions are listed in Section 8.2.

4.3.1 Blood pressure

Self-measurement of blood pressure

Those in the participant-led online group will receive advance letters that will include a request to sample members to get their blood pressure measured at home if they have the required equipment available or alternatively at a pharmacy offering free blood pressure checks or their GP surgery, prior to completing the questionnaire online. The advance letter will include a card to record the blood pressure which will then be reported during the interview.

For those invited to a face-to-face interview who switch to web, they will be provided with the same information by the interviewer if they arrange the switch to web for the participant, or via the reissue letter if we are asking them to complete by web because they failed to respond to the invitation to a face-to-face interview.

If a participant's blood pressure is outside the normal range (see below for details) when entered online, a pop-up box will recommend that the participant seeks medical advice through their GP.

If the participant has not been able to get their blood pressure measured before the interview, they will be sent a letter after their interview and invited to return the measurement card to the university using the Freepost envelope enclosed with the advance letter if they are able to get a measurement after the interview, or to enter their results in a secure online form. For those who complete their survey online, we would write to any participant with blood pressure measure outside of normal ranges.

² https://www.understandingsociety.ac.uk/sites/default/files/downloads/documentation/mainstage/user-guides/6614_Cognitive_Ability_measures_v1.1.pdf

Measurement of blood pressure during interview

During the face-to-face appointment, direct measurements of blood pressure will be carried out by the interviewer using an automated sphygmomanometer. This will produce a reading for systolic and diastolic blood pressure and pulse.

Three measurements of each participant's blood pressure will be taken. Results will be recorded in CAPI, and reported to the participant if requested.

Feedback of blood pressure results

However measured, if the lowest blood pressure reading is greater than or equal to 140/90mmHg, the participant will be advised that their blood pressure is high and would be advised to seek medical advice through their GP. However, if the participant's blood pressure is extremely high (e.g., greater than or equal to 180/115mmHg) then with the participant's consent, the interviewer would contact the survey doctor immediately after the interview or a data flow will trigger this from the online survey. The doctor would then make a decision whether they should follow this up with the participant.

Participants with extremely high blood pressure readings will be told that the survey doctor will be informed about the reading and that the survey doctor may wish to contact the participant to follow up.

4.3.2 Body weight and height

In the face-to-face interview, participants will be asked for permission to have their standing height and weight measured. The scales used will also use bio-impedance to calculate measures of body fat and body water percentage. If participants ask to be given their height and weight measurements taken on the day, the interviewer will feedback these measurements.

4.3.3 Waist and hip measurements

Self-measure of waist and hips

Those in the participant-led online group will receive advance letters that will include a tape measure and a request to the sample member to measure the circumference of their waist and hips. Those in the interviewer-led population sample who complete online will also receive a letter containing the tape measure. Full information on how to take these measures accurately will be included in the information leaflet enclosed with the letter. Sample members will be asked to write their measurements on the measurement card which they can also use to record blood pressure. The participant will then report their measures during the interview. If the participant has not been able to measure their waist and hips before the interview, they will be invited to return the measurement card to the university using the Freepost envelope enclosed with the advance letter if they are able to take these measurements after the interview.

Measure of waist and hips within the interview

During the face-to-face appointment, the interviewer will supervise the participant measuring their waist and hips. The interviewer will give the participant a tape measure, and then supervise as the participant measures their own waist and hips, making sure that the measurements are taken according to the measurement protocol.

4.3.4 Body Volume app

During the interview participants with an iOS or Android smartphone will be invited to download the “BodyVolume” app. This is an application that was developed for Understanding Society by Select Research Ltd. and implemented on the 15th wave of the Innovation Panel. The participant may download the app during the interview but will be asked to complete the measurement after the interview, and for those interviewed face-to-face, after the interviewer has left the household. The BodyVolume app collects basic information about the participant (sex, age, self-reported height and weight, and activity status). The participant can then use the app to take a scan of their body, using the camera in the smartphone. The app requests that the participant takes two scans – one of their body facing the camera, and a second with the participant facing sideways. The app turns these scans into outlines, and then calculates a range of physical measurements from the outlines. The results of these scans are available to the participant in the “results” section of the app.

Once these have been viewed, the participant has the option to upload the data from the scans to the Select Research servers. The photos are not uploaded to the servers, only the data. The app calculates measures of waist-hip ratio, waist circumference, total body fat, visceral fat, and lengths of body parts (e.g., right length of inside leg from crotch to floor). The participant can delete the app once the data are uploaded.

4.4 Collection of new human tissue samples

During the survey, participants will be asked if they are willing to participate in the collection of blood and, for a subsample, stool samples. If they consent, participants will be posted kits to enable them to provide a blood sample and a stool sample. Participants can consent to none, one, or both of the biomarker collections.

The questionnaire will include the consent questions. For those completing online, it will also include a link to the participant information sheet/s. For those interviewed by an interviewer, the participant information sheet will be handed over. The participant will then be asked the consent question.

4.4.1 Collection of blood samples

For the blood sample collection, the question will ask: “Do you consent to provide a blood sample that will be analysed by Thriva for these tests?”. If they consent, a follow-up question asks “If you want, we are able to send the results of your HDL, total cholesterol and HbA1c levels from your blood sample. Do you consent for these results to be sent back to you?”.

If the participant consents to providing a blood sample, they will be sent the necessary kit. This will require Kantar to send Thriva, the laboratory responsible for the blood sample collection, the contact details and individual identifier code of those who have agreed to have kit sent to them. This data will be transferred using a secure and encrypted way.

During the pilot, the blood will not be stored, and it will not be used for future analyses. Once the blood has been analysed for the pilot, any excess blood will be safely destroyed.

The sample collection kits will include detailed protocols to collect the samples, including links to blood sample collection animation on the *Understanding Society* website. The animation will be specific to the procedures detailed in the attached protocols.

The blood sample collection kits will also include information on how to return the sample. The blood samples are returned to Thriva through the post. Thriva will manage the process of sending out the blood sample kit and recording the returned kits. Participants who have been sent a kit, but where it has not been returned after 10 days and 20 days will be sent a reminder letter/email from Kantar. To enable this, Thriva will upload a secure file of identifiers to an sftp site to which Kantar has access. Thriva will analyse the blood and upload the data to a secure and encrypted portal accessible only to a small number of Understanding Society data managers at ISER and Kantar. Kantar are responsible for sending out the results letters and incentives to those who have returned a blood sample. ISER will identify any high risk results in the data and pass these on to the Survey Doctor (see 4.4.2 below). Thriva are accredited to the ISO27001 standard for Information Security Management.

The blood sample collection kit enables participants to collect a finger-prick capillary blood sample. The outer packaging will have a clearly identifiable UN Hazard Logo (UN3373).

4.4.2 Feedback of blood results

If participants consent to receiving their blood results for HbA1c, HDL and total cholesterol once available they will be sent their results. Participants' results will be returned as falling within a range and not a specific value (e.g. not a clinical diagnosis). These levels are defined as follows for whole blood samples:

HDL:

Below normal: < 1mmol/L

Normal: 1mmol/L and above

HbA1c:

Below diabetes cut point: 47 mmol/mol or less

Diabetes: 48 mmol/mol or over

Total Cholesterol:

Normal: 5mmol/L or less

Above normal: >5mmol/L

Kantar will send feedback letters to all participants who provide a blood sample and have consented to have the results sent to them. For participants whose results are high, the letter will include a recommendation to see their GP. Where the results indicate an adverse finding, ISER will consult with the Survey Doctor. The Doctor will review the results and other information on the participant and decide what to do. Given the analytes we are measuring, it is unlikely that any results will indicate a life-threatening issue, but in the event of this occurring, Thriva will contact ISER by email, and we will consult with the Survey Doctor.

4.4.3 Collection of microbiome samples

For the sub-sample invited to provide a microbiome sample, the question will ask for permission to provide a sample that will be analysed by the Quadram Institute for sample quality. During the pilot we will record who agreed to have a kit sent to them, who returned a kit, and the quality of the sample. We will only be analysing the microbiome samples for quality control purposes for the pilot, to ensure that implementing this design on the full Wave 16 will provide high quality samples.

If participants consent to the statement, they will be sent a DNA Genotek OMNIgene GUT kit with instructions on how to provide a stool sample. If the participant is willing and able to provide a sample, they will then return the packaged sample back to the University of Essex. On arrival at the University of Essex, the parcel will be securely transported to a laboratory at the School of Life Sciences. Then the samples will be sent to the Quadram Institute Bioscience who will analyse the stool samples and give an assessment of the quality of the samples.

The OMNIgene GUT collection kit is designed to be used in the home by non-medically trained people, enabling microbial DNA to be collected. It is the preferred

approach when a cold chain is not feasible as it is stable at room temperature for 60 days (Choo, Leong, Rogers, 2015).

4.5 Incentives for participation

For those who have participated in the survey at the previous wave, £20 Love2Shop unconditional gift-cards will be included with the advance letter as a token of appreciation for their continued involvement in the study. Those who did not participate at the previous wave will be offered a £20 Love2Shop gift-card if they take part in the pilot. In the participant-led web mode, if the online questionnaire is completed within the first five weeks of being invited to participate, the participants will be given an additional £10 token of appreciation. These amounts are the same as those used on the main *Understanding Society* study.

The advance letter includes a change-of-address section. If a sample member informs the university of a change of address, they are sent a £5 Love2Shop voucher. In addition, those who return a blood or stool sample are sent a £5 Love2Shop gift-card for each sample type.

5. STUDY SETTING

Face-to-face interviews will be conducted by experienced interviewers using computer assisted personal interviews (CAPI) in the home of the participants. Currently, the following protocols are in place for conducting in person interviews in homes due to coronavirus.

1. The interviewers will assess their own health at the start of every working day, and will not work if they display symptoms of COVID-19 in the last five days;
2. Social distancing will be observed by interviewers. Interviews will be conducted with a one metre social distance;
3. Interviewers are provided with face masks. Interviewers may choose to wear these whilst working and the participant will be asked prior to the interview if they would like the interviewer to wear a mask in their home. The interviewer

will sanitise their hands and equipment before entering the participant's home and during the interview if they need to pass anything to the participant;

4. The participant will be asked, prior to the interview, to choose a place where they and the interviewer can sit at least one metre apart. Furthermore, they will be asked if they could open a door or window for ten minutes, every hour, to provide ventilation in the room where the interview will take place.

These will be updated according to MRS guidelines in place during fieldwork. If appropriate, we will submit amendments to the ethics committee if/when such processes change. In the web group, participants will complete the questionnaire online on a desk pc, tablet or other device, and could be anywhere when they do this.

6. STUDY SAMPLE

Understanding Society is a longitudinal survey. Participants in the pilot sample have already been recruited and have been interviewed at least once. The pilot sample used for the Wave 16 pilot comprises of two groups:

1. 2008 Pilot sample. This sample was first recruited in 2008 to test the data collection instruments and fieldwork procedures in advance of Wave 1 of *Understanding Society*. The pilot sample was issued annually prior to each wave of data collection until Wave 9 (2016). This pilot sample was then used to pilot the biomarker data collection at IP12 (2019).
2. 2022 Pilot sample. This sample was recruited as a web-only pilot sample in 2022, using the Wave 14 questionnaire. Those who took part in the 2022 recruitment will be issued for the Wave 16 pilot.

The sample for the Wave 16 pilot will consist of around 300 addresses in England and Scotland.

A random half of households in the pilot sample will be allocated to the group who will be asked for permission to send a kit to allow them to collect and return a stool sample.

Study inclusion criteria

To be included in the Wave 16 pilot:

- A person must be part of a household that has taken part in one or more previous surveys.
- Reside in England or Scotland
- Participants need to speak English

Inclusion criteria for questionnaire component:

- Agree to participate in a face-to-face interview with an interviewer or be willing to complete the web-based questionnaire.
- Participants need to be aged 16 years and over

Inclusion criteria for bio-measures:

- Agree to participate in bio-measure collection or willing to collect/provide biological samples.
- Be willing to provide consent for collection of biological samples during the interview.
- Not fall within any of the exclusion criteria for each bio-measure listed.
- Participants need to be aged 16 years and over for collection of all bio-measures and blood samples.

Study exclusion criteria

To be excluded from the Wave 16 pilot:

- a participant or household based outside England, or Scotland.
- a participant who has notified the study that they wish to withdraw from the study
- a participant who has declined to participate on receiving the advance letter
- a participant who has declined to participate when the interviewer calls to make an appointment
- a participant who does not speak English
- at the face-to-face interviews if the interviewer feels a participant is not capable of providing informed consent, the participant will not be included in the study

Bio-measure specific exclusion criteria are included below, in Section 8.2.

The geographical and linguistic restrictions only apply to the pilot. In the main Wave 16 data collection, the sample will be households in the UK, and the questionnaire and documents will be translated into nine other languages.

7. INFORMED CONSENT

Participants will be provided with detailed information sheets detailing the nature of the study, what it will involve for the participant, and any risks involved in taking part. It will be clearly stated that the participant is free to withdraw from the Study at any time for any reason with no obligation to give the reason for withdrawal.

The participant will be allowed as much time as wished to consider the information given to them, and the opportunity to question the interviewer or in the web-first group, to contact the Study, prior to making a decision if they wish to participate in the Study.

Adult participants (meeting all inclusion criteria for collecting biological samples) must personally consent to the consent questions, before any measures or sample collections are carried out, this is recorded within the survey software (online or in person). Those who have provided their email will receive an email notification after the interview to acknowledge that they have given consent.

7.1 Questionnaire component of survey

Participants in both groups will be sent an advance letter that will say that participation is voluntary. Participants have opportunities to ask questions or withdraw from the Study using the details provided in the advance letter at this stage, or when the interviewer contacts participants to make an appointment or during the interviewer visits. Participants assigned to the participant-led web mode are free to withdraw from the Study or contact the Study with any questions they have at any point using the details in the advance letter. Participants can make use of freepost, Freephone, email or the study website to contact Study personnel.

From the time of the advance mailing to the interviewer appointment, there is sufficient time for a person to decide whether to participate. Interviewers will also inform participants that they may refuse to answer individual questions or only

participate in certain elements of the bio-measure component of the Study. Participants have been interviewed in at least one previous wave of the Study, and therefore are aware of the survey process and the type of questions asked in the survey.

7.2 Collection of human tissue samples

Consent will be requested from adult participants (aged 16 years and over) for the collection of blood and microbiome samples. The decision of the participant will be recorded during the interview. Only those who consent to having the kit sent to them, collecting the sample, and – in the case of blood – having the sample analysed will be sent the appropriate kit(s). Once the kit is received, the participant can decide whether or not they want to use the kit to collect the sample, and whether or not they want to return the sample.

7.3 Collection of other bio-measures (blood pressure, height and weight, waist and hip circumference)

In the face-to-face interview, verbal consent will be requested from participants prior to the measurements being carried out. This will be recorded in CAPI.

The type of consent sought for each component of the study is summarised in Table 3 (below).

Table 3: Type of consent for each component

Adult participants	
Measure	Type of consent from participant
Questionnaire	Verbal consent (recorded on CAPI or online)
Self-measurement of blood pressure	Implied consent (by taking and recording blood pressure)
Height	Verbal consent (recorded on CAPI)
Weight and body fat	Verbal consent (recorded on CAPI)
Self-measurement of waist/hip circumference	Implied consent (by taking and recording waist/hip circumference)
Waist/hip circumference	Verbal consent (recorded on CAPI)
Interviewer administered blood pressure measurement	Verbal consent (recorded on CAPI)
Self-collected blood sample	Verbal consent (recorded during interview - in person and online) and implied consent (by returning the sample)
Feedback of selected blood results	Verbal consent (recorded during interview – in person and online)
Self-collected microbiome sample	Verbal consent (recorded during interview- in person and online) and implied consent (by returning the sample)
Body Volume (app)	Implied consent (by downloading and installing app, by launching the app and using it to take scans, by allowing the app to upload the scan data)

8. ETHICAL AND REGULATORY CONSIDERATIONS

8.1 Assessment and management of risk

The study is low risk overall. The primary potential risk is a breach of confidentiality. Since the BHPS – Understanding Society’s predecessor study – was established in 1991 there have only been a small number of data security incidents by the fieldwork contractors. In each case, the incident was reported and monitored according to the incident management procedures. The incidents were investigated by the fieldwork agencies and additional measures put in place to minimise the risk of a repeat of the incident. Systems in place for *Understanding Society* at the University of Essex, and subcontractors Thriva, Kantar Public and NatCen, meet the standards required by ISO27001.

There is a slight risk that some participants may feel embarrassment or distress related to specific questions or providing biological samples. This is dealt with in several ways. The interviewers are trained to be sensitive to such responses and to treat participants sympathetically. Participants are informed that their overall participation and responses to any particular question(s) are voluntary and that they do not have to answer every question put to them or provide any of the biological samples. Participants who complete the questionnaire online do not have to answer each question and can skip those questions they feel uncomfortable answering.

Blood and stool samples will only be collected using a kit designed to be used in the home by non-medically trained people. The kit used to collect blood has been successfully used on the *Understanding Society* COVID-19 Study as well as on a large number of other general population studies. Some individuals might experience some minor discomfort or a little bleeding from the self-collected blood sample. However, the effects are minor and should not persist beyond a few days. Participants will be advised to stop the sample collection process immediately in the event of feeling faint. Participants will be advised to be sitting down during the collection of all blood samples.

8.2 Minimizing the risks to participants

Interviewer training plays a central role in reducing risk and burden for research participants. The bio-measure training involves specification of training objectives for each measure, use of multiple methods of instruction, hands-on practice and feedback, certification and refresher training. Therefore interviewers that will be conducting the fieldwork will be well trained, provided with guidance including the support of a study doctor. Those who complete online will have access to information leaflets and links to the *Understanding Society* website with more information about the study.

To ensure participant safety and wellbeing, the following exclusion criteria apply to the bio-measure component of the survey

Bio-measure specific exclusion criteria

- Any participant who does not provide informed consent will be excluded from the blood and microbiome sample collections.
- Participants not willing to participate in the bio-measure component of the study or those not willing to provide biological samples (participants can consent to participate in the questionnaire component of the survey only).
- Participants who are pregnant at the time of interview.

The following **additional** exclusion criteria apply for each of the bio-measure experiments:

- Height and weight:
 - Participants who are chair-bound/ in a wheelchair will not have their height measured.
 - Any participant who appears to be heavier than the maximum limit of the scales (31st 6lb) will not have their body weight measurement taken
 - Participants whose height has been measured as being under 100cm or greater than 220cm will not have their bio-impedance measures taken
 - Participants fitted with a pacemaker or internal defibrillator will not have the bio-impedance measures taken

- Waist and Hips
 - Any participant who appears to be larger than the maximum length of the tape measure will not be asked to measure themselves during interview.
- Finger-prick capillary blood sample:
 - Participants with clotting or bleeding disorders
 - Participants who are currently on anti-coagulant medication (e.g. Warfarin, Sinthrome (Acenocoumarol), Pradaxa (Dabigatran Etexilate), Xarelto (Rivaroxaban) or Phenindione)
 - Women who have had a recent mastectomy and there is swelling of the arm
 - Participants who are on renal dialysis
 - Participants who volunteer that they are HIV, Hepatitis B or Hepatitis C positive, will not have a blood sample taken.
- Microbiome sample:
 - Participants who have a colostomy or ileostomy
 - Participants who have taken antibiotics or antifungal medicine in the past 6 months

Every appointment begins with a statement reminding participants that everything they say is confidential and they can refuse any question/providing a sample and the interviewer will simply move onto the next stage.

In order to maintain confidentiality great care is taken in all parts of the Study. In order to conduct the survey, personal information (including names and addresses) must be provided by the Institute for Social and Economic Research (ISER) to the subcontractors, Kantar Public, NatCen Social Research, and Thriva. The subcontractors are bound by contract to preserve the confidentiality of the information under the terms of the Data Protection Act, the General Data Protection Regulation and ISER's code of Ethics. ISER, Thriva, and all fieldwork subcontractors on this project are certified to the ISO 27001 standard for information security.

The interviewers' laptops contain the questionnaire responses, including the participant contact information, prior to them being electronically transferred to the subcontractor's office. The computers and their hard drives are password protected and encrypted. Interviewers are also bound to preserve the confidentiality of the

information under the subcontract agreement and their terms of employment. The files are encrypted when transferred. Those who complete their interview online will be automatically saving their responses to the secure Kantar servers. Following the survey, data will be transferred electronically to ISER's secure servers. At this point the sample information (names, addresses, dates of birth) is split off and stored separately from the survey data. The field identifiers are replaced with public release identifiers, and these data are then made available to ISER data team via networked computers to prepare for onward sharing.

8.3 Research Ethics Committee (REC) and other Regulatory review and reports.

Following Sponsor approval, the protocol, fieldwork documents (e.g. advance letters, participant information sheets, consent forms, sample collection protocols) informed consent form, participant information sheet have been submitted to an NHS Research Ethics Committee: East of England - Essex Research Ethics Committee. The application received a favourable opinion, REC reference 22/EE/0260; IRAS Project ID 319149.

The Chief Investigator will ensure that this study is conducted in accordance with the principles of the Declaration of Helsinki, in accordance with relevant regulations and with Good Clinical Practice.

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