PHR Project:16/09/13 - What are the health and health inequalities impacts of the **Big Local community empowerment initiative in England? Version Control Table:** Version 3: September 2020 RESEARCH PROTOCOL FOR FHM RESEARCH ETHICS COMMITTEE NIHR PUBLIC HEALTH RESEARCH PROGRAMME: What are the health and health inequalities impacts of the Big Local community empowerment initiative in England? Professor Jennie Popay, Division of Health Research j.popay@lancaster.ac.uk Contact michelle.collins@lancaster.ac.uk

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Background and Introduction

Why study community empowerment initiatives?

A growing body of evidence documents the importance for health of the control people have over decisions impacting on their lives. Theory also suggests that inequalities in control across social groups may play a significant part in producing social inequalities in health. This evidence has led to empowerment of individuals and communities being central to national and global public health strategies to reduce inequalities in health. Despite intense effort and public investment in initiatives using varying degrees of community empowerment in disadvantaged neighbourhoods in the UK, there has been little in-depth evaluation of their effectiveness in reducing health inequalities. To strengthen initiatives and inform future decision-making, more evidence is needed on effective ways to support community empowerment in ways that enhance health and reduce inequalities.

Against this background, the NIHR School for Public Health Research (SPHR) developed phases 1 and 2 of the Communities in Control study (CiC) within its Health Inequalities theme. The current proposal for a 3rd phase of the CiC study was developed in response to the NIHR Public Health Research programme funding call *Which interventions, using a community engagement approach, are effective in improving health and wellbeing and reducing health inequalities?*

The Big Local initiative, supported by the Big Lottery Fund and managed by Local Trust, provides a rare opportunity to exploit a 'natural policy experiment' in community empowerment for evaluation purposes in 150 neighbourhoods across England. CiC phase 3 intends to continue to develop the evidence base on community empowerment and health outcomes through a multi-phase study evaluating the implementation and impact of the Big Local programme.

The intervention

Big Local (BL) is an area-based initiative, funded by the Big Lottery Fund and administered by Local Trust (LT). Under BL, 150 relatively disadvantaged neighbourhoods in England will each receive at least £1 million to spend over a ten-year period. Areas have joined the programme in three waves each of 50 areas, in July 2011, February 2012 and December 2012. BL takes an asset-based approach, seeking to accentuate positive capabilities of individuals and populations to identify local priorities and take action to address these. (Morgan and Ziglio, 2007). LT, the national agency responsible for delivering the intervention, has developed a programme logic model which posits collective control by residents as the vehicle for delivering improvements in the local area through three pathways. These pathways are social, economic and environmental development (positioning change around

people, place and economics) - leading to four key outcomes: (i) communities better able to identify local needs and take action in response to them (ii) people with increased skills and confidence, so that they continue to identify and respond to needs in the future (iii) communities making a difference to the needs they prioritise and (iv) people feeling that their area is an even better place to live. Though this logic model currently does not consider potential health outcomes in theory, *BL* could contribute to a reduction in health inequalities by improving the health of residents in these neighbourhoods faster than the average because (i) it focuses on improving key social determinants of health inequalities; and (ii) aims to do this by enhancing the collective control of residents over how their neighbourhood can be improved.

Each *BL* area is required to establish a partnership to oversee the initiative involving a majority of residents as well as representatives of other local agencies; and to develop a plan that is endorsed by LT. In this regard, the 'function' of the *BL* intervention as set out in the programme logic model is standardised across the 150 *BL* areas and local partnerships are expected to progress along a pre-defined seven-stage pathway (for example, developing visions, setting up partnerships, developing plans). There will, however, be variation in the form the intervention takes within areas (see Orton et al. 2017) which can be exploited for evaluation purposes.

The standard approach to evaluation of social and health interventions is to ask questions about 'what works' or 'does not work', for whom and in what contexts. The answers to these types of questions, however, whilst important, are not sufficient when the focus is on complex, socially- embedded interventions, where pathways to impact are never linear or predictable and the varying and often unstable context is of crucial importance. As Petticrew (2015) argues, in addition to asking 'what works' evaluation should also ask 'what happens' when an intervention is "implemented across a range of contexts, populations and subpopulations, and how have these effects come about?". This focus shifts the orientation for evaluation towards investigating the chain of events flowing from the introduction of an intervention in a complex, adaptive system and producing evidence that informs decisions about how to make things happen more effectively in the future (Hawe et al, 2009; Diez Roux, 2011; Angeles et al, 2014).

The Communities in Control study

The Communities in Control (CiC) study is a 'natural experiment' in community empowerment. By 'natural experiment', we mean "Events, interventions and policies that are not under the control of the researchers, but which are amenable to research using the

variation in exposure that they generate to analyse their impact"(MRC, 2011). No aspect of the BL initiative is under the control of the researchers, but there are variations across the 150 neighbourhoods which can be exploited for evaluation purposes. Firstly, there is variation between BL areas, with local partnerships developing different approaches that respond to locally defined needs. Second, there are differences in the social, economic and political contexts in which programmes are rolled out. These differing contexts could lead to differences in impact of BL on health and other outcomes. Thirdly, there is variation over time within BL areas as there is no fixed BL timescale, leading to variation in the pace and scale of roll out. Comparisons within areas over time are therefore possible. There is also potential variation between BL and matched comparator areas.

Phase 1 of the CiC study

During Phase 1 of the SPHR funded research which ran from January 2014 to December 2015 we began to develop geographically linked datasets covering each BL area, including a limited range of variables from the census. These datasets were used to explore different ways of characterizing and measuring local 'context'. In addition, analyses of qualitative data collected during this first phase contributed to important conceptual clarification about the effects of local context on the nature and delivery of the BL intervention (Orton et al., 2017).

In the qualitative fieldwork, four types of participative spaces associated with BL were identified: the partnership space, the resident space, the project space and the event space. We also began to identify critical processes that can amplify or dampen the positive potential of these spaces. We have identified provisional markers of capability for, and the exercise of, collective control by BL residents: increases in connections and networks with other organisations and evidence of attracting resources/matched funding for local environmental improvements or successful advocacy for change.

Phase 1 findings also illuminated ways in which processes of inclusion and exclusion are operating amongst different sub-groups within BL populations and pointed to the potential for different approaches to participation to impact differentially on the experience of collective control amongst these sub-groups.

Finally, findings from phase 1 highlighted the diverse ways in which the money given to the BL communities under the initiative can 'work' as a mechanism for supporting and sustaining residents' collective control of decisions and/or actions that can improve their neighbourhood. There are symbolic, practical and paradoxical dimensions of the way the money works. Negative aspects were also identified, including tensions around how the money should be used, who has entitlement and the practicalities of the day-to-day governance of the money.

We also obtained preliminary insights into the circumstances in which the money has amplifying and dampening effects on residents' capability for and exercise of collective control.

Phase 2 of the CiC study

The early findings from Phase 1 then fed into the design for the Phase 2 which ran from October 2015 to March 2017. Phase 2 involved four work-packages. WP1 'Understanding system changes that influence residents capability for collective control comprised three elements (i) qualitative systems analyses in 15 BL neighbourhoods; (ii) analysis of critical incidents of collective control in up to 5 further BL neighbourhoods; and (iii) exploratory work on the potential contribution of system dynamics and agent-based modelling. WP2 'Understanding the experience and impact of BL on engaged residents' involved a longitudinal survey of BL activists in the15 'neighbourhood' fieldwork sites and analyses of data from a survey of partnership members in all 150 BL sites conducted by LT. WP3 sought to identify types of context, implementation progress and approaches to resident participation across BL areas for internal comparisons. Exploratory work on the economics of BL has also been undertaken.

Phases 1 and 2 of the study received ethical approval from Lancaster University FHM Ethics Committee and colleagues based at other universities followed the requirements of their own institutions for local approval.

We are seeking ethical approval for phase 3 of the Communities in Control study: What are the health and health inequalities impacts of the Big Local community empowerment initiative in England?

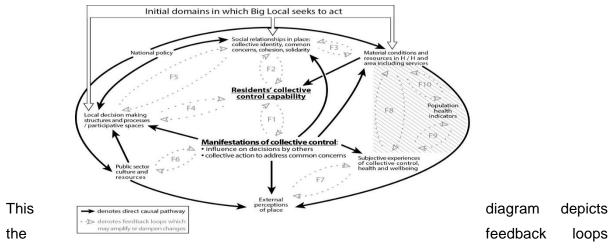
Phase 3 of the CiC study

The third phase of the Communities in Control aims to investigate health and social outcomes of BL approaches to community empowerment including its impact on health inequalities and to draw out learning for the development and implementation of future community engagement interventions. The objectives are to: (1) Investigate longer-term health and social outcomes of BL approach to community engagement at population health level; (2) Investigate the impact of active involvement in BL on the health and wellbeing of engaged residents; (3) Assess changes in collective control capability amongst BL residents and identify any resulting improvements/deteriorations in social determinants of health inequalities; (4) Increase understanding of pathways to changes in the capability for and/or exercise of collective control by BL residents and any effects on health or social outcomes;

(5) Conduct an economic evaluation of BL; (6) Draw out policy, practice and research implications for future community engagement strategies.

A key element of CiC is the development and use of the Collective Control Influence (CCI) system. See Figure 1 below.

Figure 1: Collective Control Influence System



triggered by BL that will enable and/or constrain (in systems language - amplify or dampen) residents' attempts to improve the conditions in which they live through actions that ultimately may improve population health in these neighbourhoods. In doing so, these processes may contribute to a reduction in health inequalities in the longer term.

Based on empirical data from phases 1 and 2 of research, we hypothesised two main pathways from the BL to health and social outcomes at the level of the neighbourhood population and at the level of active residents. The first operates through increases in the capability for collective control amongst BL residents. The second operates through the exercise of collective control by residents acting to influence the decisions of others and/or to directly change determinants of health and health inequalities. The three large white arrows in Figure 1 show the points in the CCIF system where the initial impacts of the BL would be expected to be felt: in social relationships in place; local decision-making structures and processes; and material resources in households and the environment. Various complex interactions between elements of the system flow from these initial impacts. In Figure 1, proposed direct causal links between different elements of the CCIF system are shown with a solid line and arrow, whilst feedback loops between these are shown with a dotted line (F1-10).

Our logic model for 'what happens' in the CCIF system when BL is implemented and how these perturbations in the system might lead to health outcomes starts from the premise that greater collective control/empowerment may result when community members act together for mutual benefit (Whitehead et al. 2014). If, in gaining greater collective control, residents are able to prevent or mitigate exposure to health damaging conditions (e.g. by working directly or with others to improve the social determinants of health), then direct health effects may ensue through making their neighbourhood a healthier, better place to live. There may also be indirect health improvements arising from the reduction in social isolation and improvement in mental health that participation in community action may bring about. Finally, increased control may lead indirectly to physical health benefits. Evidence from the work environment shows that employees who experience high job demands but low control over their working conditions are at higher risk of psychosocial stress, which has been linked to physical conditions such as coronary heart disease. Furthermore, exposure to low job control increases with decreasing social position and may have contributed to the observed social inequalities in coronary heart disease incidence. Changes in physical health conditions, such as coronary heart disease would only be expected to emerge in the longer-term, unlikely in the lifespan of this project.

Study Design

We propose four work packages, each designed to address one or more of the study objectives. Our 39 month timeline has been designed to maximize the availability of secondary data on the social and health impact of BL at the population level and particularly on engaged residents.

Work Package 1. Assessing population level impact on health and social outcomes.

Addresses study objective 1: To investigate longer-term health and social impacts of the BL approach to community engagement at the population health level.

Timelines: This work package will extend across the 39 months of the project but intensive analysis will take place in the last 24 months from December 2019 to May 2021.

Approach: We will use a differences-in-differences design to investigate the impact of BL on population health and social outcomes in BL areas compared to matched comparator areas. We have mapped the BL geography onto 844 lower layer super output areas (LSOAs) and have then used propensity scores to match these areas on a 3:1 basis with comparator areas that are similar in terms of deprivation, ethnicity, age profile and baseline health indicators

Data sources: We will use the ONS Annual Population Survey and extend the existing BL neighbourhood-level secondary datasets developed for each BL area during the SPHR funded research. This work will involve the construction of an 11-year annual panel dataset

(2010- 2020) of outcome data. The 2020 limit relates to the routine data we will be using. In addition we will draw on Hospital Episode Statistics, NHS Digital GP prescribing data and Police recorded crimes and incidents of anti-social behaviour.

Obtaining and managing the data: Data from the ONS Annual Population Survey will be accessed under special license through the UK Data Service through which we will sign a Secure Access agreement. A Special Licence means that the data is anonymised and can only be accessed by approved individuals for a specified usage and for a specified period of time. Data will be stored in accordance with the responsibilities set out in the UK Data Archive document Microdata Handling and Security: Guide to Good Practice (https://www.ukdataservice.ac.uk/media/604725/cd171-microdatahandling.pdf). This document includes requirements that the data be stored on pass-phrase protected PCs or laptops in a room not accessible to the general public, portable or printed copies must be stored in a locked cabinet with restricted access. As part of the Special Licence agreement for the ONS data we undertake to delete this data at the completion of the project, Ben Barr at University of Liverpool will take responsibility for ensuring this happens.

Hospital Episode Statistics will be obtained through our current data sharing agreement with NHS Digital (DARS-NIC-16656-D9B5Tv2.2). Data will be transferred by NHS Digital using Secure Electronic File Transfer (SEFT) which can only be accessed by people who are registered and approved users.

NHS Digital GP prescribing data are Open Data and will be downloaded from NHS Digital website.

Recorded crimes and incidents of anti-social behaviour are Open Data and will be downloaded from https://www.gov.uk/government/collections/crime-statistics

The non-APS data will be stored in electronic form on secure university servers and accessed through password protected networked PCs or laptops. Portable or printed copies of the data will be stored in locked cabinets in a room with restricted access. Ben Barr at the University of Liverpool will take responsibility for ensuring that these data are deleted at the end of the project.

All secondary data-sets generated for this project and held centrally at Lancaster University will be stored in either electronic or paper form for a minimum of 10 years after the end of the project. Data in electronic form will be stored in a project folder with named members of the research team having access to it. Dr Katharina Janke will be responsible for ensuring that the data that is not sharable are deleted after 10 years.

Constructed comparators: The 844 small census areas (LSOAs) within BL areas have been matched on a 3:1 basis with 2532 comparator LSOAs based on a range of baseline characteristics. We initially used logistic regression to calculate the predicted probability that each LSOA in England had of being included in a BL area using indicators of socioeconomic deprivation, population health, ethnicity and age profile. We then used these 'propensity scores' (Austin, 2011) to match each BL LSOA with 3 non-BL LSOAs with similar baseline characteristics.

Outcome measures: We have chosen outcome measures based on our earlier work on identifying theories of change from previously published studies, primary research on the impact of New Deal for Communities on health inequalities, our earlier SPHR funded research in BL communities and a careful assessment of routinely available data sources available to all BL areas. This body of work points to the theoretical utility of a number of psychosocial, social and material pathways to subjective mental health and wellbeing outcomes along with secondary outcomes that include health service utilization and social outcomes such as crime.

Our previous work indicates that community empowerment initiatives are likely to have a greater impact on mental rather physical health in the short to medium term. Anxiety has previously been theorized as both an outcome of collective control in its own right, and an important intermediary point to further behavioural, social and health impacts. (Whitehead et al, 2016; Griffin et al., 2002; Schrijvers et al. 2002; Wilkinson, 1999). Therefore, our primary outcome will be high levels of anxiety self- reported in the Annual Population Survey (APS), measured as the proportion of people reporting a score of more than 6 in response to the question "Overall, how anxious did you feel yesterday?", where 0 is 'not at all anxious' and 10 is 'completely anxious' (Outcome 1). A threshold of more than 6 on the 11-point scale has been identified by the ONS as a measure of high anxiety levels

The APS includes three other measures of subjective wellbeing (happiness, life satisfaction and feeling worthwhile), developed by the Office for National Statistics (ONS) as part of their Measuring National Wellbeing Programme. We assessed each of the ONS wellbeing indicators to identify which was most likely to reflect changes in population mental health that would have clinical significance. In particular, we estimated the association between the change in an area's level of the wellbeing indicator and the change in an area's level of antidepressant prescribing. The proportion of respondents reporting high levels of anxiety was most closely associated with the level of antidepressant prescribing (p=0.002).

In addition we will therefore investigate the impact of BL on the following secondary outcomes:

Outcome 2: Small Area Mental Health Index (SAMHI). The SAMHI is a composite annual measure of population mental health that we have developed for each Lower Super Output Area (LSOA) in England. The data and methods used to compile the index are available data the Place-based through our open portal Longitudinal Data Resource(https://pldr.org/dataset/2noyv/small-area-mental-health-index-samhi). The SAMHI combines data on mental health from multiple routine sources into a single index (underlying measures include: antidepressant prescribing, mental health related hospital attendances, diagnoses of depression in primary care, self-reported mental health problems from the GP patient survey, and claims for Incapacity benefit and Employment support allowance for mental illness). By combining these data into a single index it provides a more precise measure than the separate measures outlined below (outcomes 3 & 4).

Outcome 23: Antidepressant prescribing measured as the average daily quantity of antidepressants prescribed per 1000 population using GP practice prescribing data provided by NHS digital.

Outcome 34: Mental health related hospital attendances per 1000 population using Hospital Episode Statistics provided by NHS Digital (A&E attendances and admitted patient care for alcohol misuse, drug misuse, self-harm and common mental disorders).

Outcome 45: Recorded crimes and incidents antisocial behaviour per 1000 population for the offence categories (violence against the person, burglary, theft, criminal damage and antisocial behaviour using Open Data available from gov.uk

These reflect the health service and welfare consequences of population mental health (outcome 2, 3 and 4) and social relationships within a place (crime and incidents of antisocial behaviour – outcome 45), reflecting pathways to health impacts in our logic model. During workshops set up to discuss this proposal BL residents confirmed the importance for them of improved mental health outcomes and also suggested that their experience supported the postulated pathway from BL involvement to improved mental health. However, residents did express concerns at the absence of socio-economic outcomes in this work package (e.g. improved working conditions, decreased debt) although it was noted that these would be investigated in Work Package 3.

Sample size: Our primary outcome comes from the APS, which has a national representative sample of 165,000 from the UK population each year. The UK Data Service makes available a secure access version of the APS that includes the LSOA in which the respondent lives. We will use this information to identify respondents in BL and in comparator areas. Based on information on the number of respondents in each local authority area, we estimate that there will be approximately 3000 respondents each year from within BL areas and 9000

respondents from the comparator areas. The data were first collected in April 2011 and we will use data to March 2020. Thus there are nine years of data, providing a total of 108,000 observations. We have used simulation methods to investigate the power that this sample would provide assuming a range of effect sizes, taking into account weights for the study design and using robust clustered standard errors to account for clustering within areas and serial correlation in the data (Feiveson, 2002). According to our calculations we would be able to detect an absolute reduction of 2 percentage points in our primary outcome, with a power of 83% (at α =0.05). Thus, if the proportion of the population reporting high levels of anxiety reduced from 21% (the baseline average value) to 19% in BL areas relative to our comparator areas our analysis would have sufficient power to detect this effect. The analysis of our secondary outcomes (2-45) will use routine data sources and be based on aggregate data for the 844 LSOAs within BL areas and the matched 2532 comparator LSOAs. Data for these indicators will be available over 11 years (2010-2020) providing 33,760 observations for the analysis. As these data are for the whole population rather than a sample survey, our analyses will recover the actual impact of BL on the population.

Analysis: We will use difference-in-difference methods to compare the change in health and social outcomes in BL areas to non-BL areas Donald & Lang, (2007). The estimate of the effect of the BL programme is therefore calculated as the difference between the change in the outcome in the BL areas and the change in the outcome in the comparator areas. This differences-indifferences approach is using comparison both within and between areas - accounting for secular trends in our outcomes and unobserved time invariant differences between areas that could confound findings. The primary assumption is that trends in outcomes would have been parallel in the BL and comparator areas in the absence of the BL programme (Donald & Lang, 2007). This is a reasonable assumption as the comparator areas are very similar to the BL areas at baseline and therefore likely to be affected in a similar way as the BL areas by wider national factors such as welfare reforms, austerity measures and economic change. We will also investigate the timing of impacts using lags for the 6 years after the intervention start date and we will also check if impacts happen before implementation of the programme using leads for the 3 years before the intervention start date

Subgroup analysis: To investigate whether contextual factors influence the effectiveness of the BL programme and potential impacts on health inequalities, we will analyse the data by the following subgroups: (1) 3 groups of BL and matched comparison areas defined by baseline deprivation using the IMD2015 score, (2) 3 groups defined by socioeconomic inequalities within BL areas (the coefficient of variation in IMD), (3) 3 groups defined by the proportion of people from non-white ethnic groups, and (4) 3 groups based on the age profile

of the population (proportion of people under 16 and over 75). In our SPHR funded research we have developed a typology based on programme intentions of each BL partnership and we will conduct a subgroup analysis based on three groups of BL areas defined by this typology.

Datasets will be compiled, prepared and checked during 2019. This work will include accessing APS data through the UK Data Service Secure Lab and developing statistical code to construct datasets and perform the analysis. Interim analysis will be performed at the beginning of 2020 and final analysis completed by March 2021.

Work Package 2. Assessing the impact of active engagement with BL on health and social outcomes in the engaged community

Addresses study objective 2: To investigate the impact of active involvement in BL on the health and well-being of residents actively participating in BL governance/activities.

Timeline: There will be some preliminary work underway from the beginning of the project but intensive work on this work package will extend from June 2018, when the next wave of the BL partnership members survey data will become available, to May 2021, allowing for linkage and analyses of cohort and cross sectional data from the 2020 partnership members survey.

Approach: There is an extensive literature demonstrating the positive health effects of participation and volunteering (Jenkinson et al. 2013) However, this research has largely included participants from higher socio-economic backgrounds and has not examined the pathways between participation (e.g. levels of control) and health. This work package will examine the long term effects of participation and collective control on health in areas that are relatively disadvantaged in socio-economic terms. Further, our programme theory suggests that if BL leads to social, economic and/or environmental improvements in the local area then the "engaged community" could benefit most in the short to medium terms at least (see Work Package 3)

Data sources: This work package will utilise secondary data from a biannual longitudinal survey conducted by LT of those most actively engaged in BL - all BL partnership board members in all 150 BL areas across England. BL partnership boards may have members from, for example, the local authority, the church, the NHS or third sector organisations but the majority of members must be BL residents. Our pilot survey showed that partnership members are representative in terms of age, gender and educational background of those most active in the BL. The Partnership Members survey is a repeat cross-sectional survey with a nested cohort. LT manages this survey biannually between May and August via an

online and/or postal questionnaire and has allowed us to include health and control questions from 2016 onwards.

LT will repeat the survey in summer 2018 and summer 2020 which gives three years of data, whereby individual records can be linked (nested cohort) within a larger repeat cross-sectional design. We obtained the wave 1 data for analysis from LT in Dec 2016.

Obtaining and managing the data: LT collates the survey responses and will send an anonymised spreadsheet of the survey dataset which will include the questions developed for the CiC study, to the analysis team in October 2018 and 2020 by uploading a copy to a shared Box folder which is only accessible to named collaborators who have been invited to join the folder. Individual records will be linked over the three waves via unique numerical identifiers for the purpose of the nested cohort. The repeat cross-sectional element will include area level data linkage. The data will be stored in electronic form on secure university servers and accessed through password protected networked PCs or laptops. Portable or printed copies of the data will be stored in locked cabinets in a room with restricted access.

Outcome measures: The survey collects data on the characteristics of BL board members (demographic data, socio-economic status), perception of individual and community control and perception of the BL area, levels of participation (number of unpaid hours per week on BL activities to aid the economic evaluation of WP4) and self-perceived health using validated 10 measures. Our primary outcome will be the Short Warwick Edinburgh Mental Wellbeing Scale (SWEMWBS), which is designed to measure positive mental health states (as opposed to symptoms of mental ill-health such as anxiety and depression). Questions include the degree to which a participant 'feels useful', 'feels relaxed', 'I think that I deal with problems well', 'I feel close to other people', 'I have been able to make up my mind about things'. We will examine the overall SWEMWBS score and also the individual sub-questions (which may be more sensitive to changes over time).

Our secondary outcome will be 'self-rated general health status' (the Census measure), which asks 'How is your health in general? Would you say it was Very good, Good, Fair, Bad, Very Bad'? From our logic model, engaged residents could be expected to experience improvements in mental wellbeing and general health as a result of reductions in social isolation as they participate in BL activities, as well as through feeling that they have greater control over decisions that affect their daily lives. An intermediate outcome will therefore be changes on perception of control over decisions reported by engaged residents. The survey asks: "How much do you agree with this statement: When people in this area get involved in their local community, they really can change the way that their area is run?" and "Do you agree or disagree that you personally can influence decisions affecting your local area?"

From our logic model, engaged residents could be expected to experience improvements in perceived control over time as a result of participation in the BL initiative, and we will investigate whether this is the case.

Population sample: Although the LT survey was conducted in 2014 it did not contain questions on health or experience of collective control. For our purposes the first wave survey was in 2016. Potential respondents were identified using a common sampling frame: all BL partnership members who submitted contact details (over 1200) as part of the annual partnership review carried out by LT were approached in 135 established BL sites via email (for an online questionnaire submission). BL representatives were also sent questionnaires by post to reach as many other partnership members as possible. This gave a total potential sample of over 1600 partnership members across all 150 BL areas. 862 participants submitted a completed wave 1 questionnaire, a response rate of over 50%. This sample provides the basis for a large nested cohort, whereby individual records can be linked over the three waves. The average SWEMWBS score – our primary outcome – for this cohort at wave 1 is 15.43 ± 4.29. 87% of the cohort agreed that people can change their community while 78% agreed that individual decisions can affect their local community.

Based on these results, the sample size for the nested cohort is within power at 90% (assuming 5% intra-site correlation) to 99% (assuming no correlation within site and no correlation between repeated data per participant) and a minimum standardized difference of 0.2 in average SEWMBES score between time points (for example, wave 2 versus wave 1 or wave 3 versus wave 2). It is anticipated that the nested cohort will not be subject to high attrition rates given the engaged nature of the respondents and the stability of the population (although those that drop out from BL activity will not be part of the sampling frame in 2018 or 2020). Assuming a non-linear change in SEWMBES score over time and 90% power, 582 participants will be required at wave 3 to detect a minimum standardized difference of 0.2 in SEWMBES scores, after adjusting for clustering of participants within sites (using 1.9 design effects and 10% intra-site correlation) and the repeated data per participants (using 20% intrasubject correlation). A significance level of 1.7% was used for the Bonferroni correction for multiple comparisons across waves 1, 2 and 3. Assuming a 25% attrition rate, a minimum of 820 participants is required at wave 1 to retain 90% power to detect changes between the follow-up waves. Appendix Table 3 shows the minimum wave 1 sample size to detect small to moderate effect size assuming 90% power and a 25% attrition rate at follow-ups. The sample size calculation was done using nQuery+nTerim 2.0.

Analysis: Statistical analysis will primarily examine whether our outcome measures change over time during the survey period. We will also examine whether any changes in subjective

assessments of individual or collective control are associated with any changes in health. For the nested cohort of linked individual level data we will use linear mixed effects model to account for the clustering of participants within sites and the repeated measures per participants across the waves. In the first instance, the different waves will be treated as categorical variables with multiple comparisons between waves. This saturated model will be compared with a simpler model that assumes linear changes over time and uses likelihood ratio test (Verbeke & Molenberghs, 2000).

The secondary outcome of 'general health' and the individual and collective control measures will be analysed using a proportional odds model to accommodate the ordinal nature of the data. This model will be fitted using generalised estimating equations to account for the repeated data within site and per participant. Additional analysis will be performed using an adjacent category logit model to check the sensitivity of the proportionality assumption. The analysis of the repeated cross-sectional data will use the same techniques. All models will adjust for age, gender, length of involvement in BL, intervention type, and time. Sensitivity analysis for missing data will be performed using a drop-out model to identify factors that are predictive of missing data. We will also run multiple imputation to investigate the impact of missing data on the results and to check whether it is safe to assume a missing at random mechanism.

Subgroup analysis: We will investigate whether there are differences in effect across a number of pre-defined groups in an exploratory approach using interactions (Petticrew et al. 2012). Firstly, we will investigate potential effects on health inequalities by analysing whether any effects differed by education or gender. Secondly, we will investigate differences in effect by area-level variation in BL activities using the typology developed in our current SPHR funded research and described briefly in section 2. Thirdly, we will investigate any differences in terms of levels of participation in the BL to see if there is a graded effect of participation on control and our health outcomes.

Constructed comparators: To control for general trends in SWEMWBS, we will create a comparator group from the 2016 and 2018 Health Survey of England (HSE), which includes WEMWBS. Propensity score matching will be used to identify HSE participants that are similar to BL members in terms of age, gender, and educational qualification. For every BL member we will identify 3 most similar HSE participants in 2016 and 2018, resulting in a total sample size of 2460 participants per year. We will use differences-in-differences methods to compare changes in SWEMWBS between 2016 and 2018 in BL members to changes in SWEMWBS between 2016 and 2018 in Comparator HSE participants while adjusting for clustering within areas using a mixed effects model. The results from propensity score

matching will be sensitised using a multivariable regression model, propensity based weighting and propensity score adjustment (Kurth, et al. 2006). A 1000 bootstrapped propensity score matching of random samples from HSE data will examine how BL impact changes for

Work Package 3: Understanding pathways to impact

Addresses study objectives 3 and 4: Assess changes in collective control capability amongst BL residents and identify any resulting improvements/deteriorations in social determinants of health inequalities; Illuminate pathways to changes in the capability for and/or exercise of collective control by BL residents (either through influencing the decisions/actions of others or acting directly to improve aspects of their neighbourhood) and to health and social impacts, including dampening/amplifying processes.

Timeline: Fieldwork and analysis will span almost the full duration of the project. Initially we planned to undertake two periods of data collection. We are still aiming to conduct two interviews with each of our sample of 'key informants' (see below) but in order to retain relationships with the fieldwork sites and maximise opportunities to retain respondents for follow on interviews we have decided that fieldwork should be continuous over this period. Following four months for ethics and preparatory work, fieldwork and analysis will begin in September 2018 and will continue until February 2021.

Approach: This work package will: (1) Track progress of a sample of examples where residents have or are attempting to exercise collective control over decisions/actions to improve their neighbourhoods; (2) Assess the nature and scale of additional resources (cash or in kind) that residents attract into their neighbourhoods as a direct result of their collective action and the extent to which these are used for potentially health-enhancing purposes; (3) Illuminate the processes operating (within and beyond BL areas) to amplify and/or dampen the impact of these attempts by residents to act collectively; (4) Assess whether and to what extent these collective efforts by BL residents do lead to improvements that would have health-related benefits (i.e. making the BL areas healthier places to live); (5) Explore residents' subjective perceptions of the impact of their collective action on their health and wellbeing and that of other residents.

There will be three elements to this work: (i) interviews with national BL stakeholders; (ii) continuation of our longitudinal qualitative research in 15 BL areas with a particular focus on what we have termed Critical Collective Control episodes; and (iii) Analysis of a range of documents including BL area plans and other programme management documents that LT are able to make available to us.

Data collection including sampling and recruitment:

Relationships with key informants are already well established in our fifteen fieldwork sites, which will reduce the time required to gain access and if necessary to recruit additional informants. It is important to acknowledge however that there will have been some turnover of BL partnership membership over time. In total each of three academic groups in the team (Newcastle, London School of Hygiene and the Liverpool and Lancaster Collaboration) will be responsible for 50 key informant interviews in five sites over a 6 month data collection period. We have also had more turn-over of research staff than originally envisaged requiring more time for new team members to develop relationships in the field.

- National level fieldwork: The purpose of this fieldwork is to obtain a strategic perspective on actions being taken by BL partnerships on barriers and enablers to progress locally but also on constraints operating nationally on the BL programme. This fieldwork will contribute evidence about mechanisms of impact embedded in BL and how such effects could be replicated in future public health interventions. Fieldwork with LT and other national stakeholders will involve formal semi-structured interviews with a purposeful sample of 6-8 LT staff and board members as well as commissioned organisations providing support to BL. Participants will be sampled for their roles in the overall programme and field of professional knowledge. Interviews will investigate the process of BL delivery, as well as adaptations in the programme over time. Secondly, interviews will draw upon participants' professional expertise in order to critique, elucidate and refine the hypothesised pathways identified in local fieldwork. As there have been significant changes to the programme and to the broader policy landscape during the research we will return to interview up to five key informants both directly linked to the BL programme and others knowledgeable about the programme and able to comment on how the programme approach fits with the wider policy landscape relevant to place based programmes and interventions aiming to reduce social and health inequalities.
- (ii) We have well established relationships with LT built up over the four years of the first two phases of Communities in Control research activity which will facilitate sampling and recruitment processes. Regular meetings between the project's principle investigator and senior researchers take place with LT. We intend to involve LT in identifying appropriate key informants for the national interviews, we might also rely upon colleagues in LT in making introductory contact with potential interviewees on our behalf. We understand the implications that this has for the anonymity of participants and will make this clear in the consent forms.
- (iii) Detailed investigation of a sample of collective control episodes in BL neighbourhoods: This work will build on extensive ethnographic fieldwork conducted in 10

BL neighbourhoods during 2013-15 and more limited data collection in an additional five BL areas in 2016/17. In ten areas we have conducted four periods of data collection and two periods in the remaining five areas. We will approach the BL Partnership Boards in the 15 fieldwork areas to re-negotiate consent for us to continue fieldwork for the study. Where this consent is agreed, we will conduct a continuous period of more tightly focused fieldwork in each neighbourhood from September 2018 to December 2020. During our current research we have been identifying instances in which residents in our 15 fieldwork areas and in other BL areas have attempted to exercise collective control over decisions/actions with potential to improve some aspects of their neighbourhoods.

Examples of these, which we term 'Critical Collective Control Episodes' (CCC episodes), are provided in Table 1 below. We propose to select one example of a CCC episode in each of our fifteen neighbourhoods to be the primary focus of the fieldwork. We will purposefully sample these CCC episodes to ensure that they include residents' collective action that is/was:

- Short term aimed at improving a specific problem (e.g. clean up streets, change a transport route) and/or improving social relationships in the area (e.g. organizing local festivals)
- Longer term aimed at improving aspects of the local area (e.g. improving access to high quality green spaces, creating new community spaces; resisting the closure of local amenities/services and/or developing alternatives for these)
- Longer term aimed at addressing large scale and chronic structural problems (e.g. increasing employment related skills, generating more and better employment opportunities, reducing indebtedness, improving housing)

Table 1: Examples Critical Collective Control Episodes

Land swap (with housing developer) and development of pocket park

Improving social relationships and cohesion by creating new/improving existing community assets and/or organising local murals and/or festivals

Action to reduce hazards from badly controlled dogs, which led to child's death due to dog attack and fouling of streets, including establishing an annual dog show

Development of and/or transferring ownership of community hubs including asset transfers

Young people's involvement in the creation of new provision e.g skatepark.

Influencing local transport strategy including parking regulations

Improving access to and quality of local services

Promoting/supporting local economy

Improving quality of and access to housing including setting up co-operatives

Management and improvement of local environment, including green/blue space

Programme of activities including community festivals to challenge negative external perceptions of the area and generate financial resources for the community.

We will also sample to include examples where residents are acting on their own or with other agencies, where they are seeking to attract additional resources to support their action and that are judged by local respondents in our current research to be making good progress/have been a success and those having more difficulties or judged to have been 'unsuccessful'. If necessary, we will include for study 2-3 CCC episodes in BL areas not included in the 15 we have worked with to date, to ensure that the sample reflects the diversity of collective action described above. We would select these from the 10 CCC episodes in non-fieldwork areas on which we collected preliminary data during phase 2 of the study.

Interviews

The neighbourhood fieldwork will involve the collection of longitudinal qualitative data from interviews with two sub-samples of key informants in each area. The first sub-sample will involve up to 5 members of the BL partnership including the chair, and other stakeholders with a system-wide perspective (e.g. BL representatives who are paid professional workers providing support to 1-3 BL areas), council officers and third sector representatives. These interviews will provide data on respondents' perception of processes operating at the neighbourhood level to amplify and/or dampen their attempts to act collectively to improve

their area (e.g. poor quality relationships with the Local Authority may operate as a dampener whilst a pre-existing vibrant third sector may amplify residents' action). Information about the nature and range of collective activities residents has been involved in since the last period of fieldwork in November/December 2016 will also be explored. The second subsample will involve interviews with up to 5 informants involved in the specific CCC episodes selected for study in each of 15 fieldwork areas (i.e. up to 150 interviews in total in the first round and 150 follow-up interviews in the second round). These interviews will provide longitudinal data on the micro processes shaping these episodes of collective action by BL residents. It is possible that in a few cases the same individuals will be recruited for inclusion in both sub-samples where they are Partnership members and actively involved in the selected CCE. We will also undertake targeted observation of two partnership meetings per area during the fieldwork and key activities relating to the CCC episodes, where this is possible.

We will draw on the recruitment and consent processes developed during the earlier phases of the study, whilst also taking into account that the fieldworkers that originally worked with the BL areas might not be available and that the membership of BL partnerships might also have changed in some cases. In most cases, and where relationships and communications with Partnership boards are well-developed as a result of the work in phases 1 and 2 of the CiC study, researchers will approach potential participants, who might already have taken part in 2-3 interviews already, directly to ask if they would be willing to be involved in the research.

Where relationships and communications are less well-developed, for example where a field work researcher is new to a BL area, we will invite the chairs and members of the BL partnerships to support the identification of key informants to take part in interviews. As well as researchers directly approaching potential interviewees, there may also be instances where an informant prefers to approach a colleague or friend first before giving us their name. This may particularly be the case where the researcher has not had previous contact with the participant or where the name of a potential participant is brought up during an interview by an informant.

In all these recruitment processes, once a potential interviewee has been identified we will provide them with an information sheet at least 24 hours before the interview, giving them time to consider their involvement, and discuss the research with them and answer any questions they may have before seeking written informed consent before the interview begins. We also will explain to all new participants that they are not obliged to take part and are free to withdraw if they wish. In order to facilitate the ability to withdraw data if requested

by participants we will keep participant details in a secure manner on password encrypted Word or Excel documents on secure university servers. These contact details will be stored separately from the data and deleted once the data have been analysed and published.

Please see annexes 1, 2, 3 and 4 for recruitment and consent materials relating to these elements of the fieldwork

Observations

There will also be some targeted observation of up to approximately six BL partnership meetings during fieldwork visits to update/check earlier assessments about the organisation and dynamics of these meetings. We might also find it necessary to observe a small number of activities or events associated with CCC episodes. It is difficult to be precise about this number until we know which CCC episodes will be the focus of our fieldwork. These meetings are most likely to relate to activities concerned with the planning and management of BL and to involve members of BL Partnerships/Steering groups, a group with whom we have and will continue to develop on-going relationships over time.

We will request permission from the organiser of the meeting and inform other necessary stakeholders informed that the research is taking place. Information will be available about the research e.g. information sheets at events. Where events involve group discussions (where the researcher might be assumed to be a participant) every effort will be made to ensure that the group leaders / facilitators as well as other individuals participating understood they are being observed for research purposes.

From our experience of observing BL partnership meetings in phases 1 and 2 we consider that it would not be appropriate to attempt to audio record consent processes. In particular, this would be disruptive to meetings that often have very busy agendas and attendees would not tolerate the time this would take up. We also have some concerns that attendees might feel apprehensive about the researcher bringing along audio-recording equipment to a meeting environment.

Please see annex 5 for recruitment and consent materials relating to this element of the fieldwork

Whilst the volume of fieldwork is significant, it will be distributed across three research teams: the Liverpool and Lancaster Collaboration (LiLaC), London School of Hygiene and Tropical Medicine (LSHTM) and Newcastle, with each academic centre responsible for collecting data in five BL neighbourhoods.

Data analysis: Research from phases 1 and 2 of CiC generated hypotheses about the pathways leading from attempts by BL residents to exercise control to potential social and health impacts at the population level and amongst engaged residents. These hypotheses include feedback loops that may amplify or dampen these impacts. Analyses of the interview data from the fieldwork in the proposed study will involve an iterative process of testing and modifying these pathway hypotheses. Formal interviews will be audio recorded and structured templates (developed during phases 1 and 2 of the research) will be used for the extraction of data from documents and for recording field notes. Line-by-line coding using NVivo and coding structures established in our previous research will be applied to interview transcripts and fieldwork notes. This will be combined with detailed memo writing. We will undertake a narrative synthesis of findings from analyses at the two levels - neighbourhood and CCC episodes. This will provide a more holistic understanding of the pathways supporting (or constraining) impact on social determinants and on health and social outcomes for the BL population and for active residents.

In phases 1 and 2 of the CiC study we developed a framework in order to type contrasting approaches to community engagement in the early stages of the BL pogramme. This typology will enable the team to identify and help explain differential impacts associated with particular BL approaches. In our evaluation of the health inequalities impact of New Deal for Communities we successfully used a similar typology approach to categorise variation in programme implementation and the role that different approaches to community engagement played (Popay et al. 2015). We intend to build on this work with the support of LT using documents and information associated with BL areas that they routinely collect and organise as part of their programme management.

Work Package 4: Economic evaluation

Addresses study objective 5: Conduct an economic evaluation of BL

Timelines: This work builds on WP1, WP2 and WP3, so it will roughly follow the timeline of these work packages. Thus, this WP will extend across the 39 months of the project but intensive analysis will take place from September 2020 to May 2021.

Approach: We propose to evaluate the economic impact of BL by conducting a cost-benefit analysis using the subjective wellbeing approach. BL is likely to affect mainly non-market goods such as health, community cohesion and the local environment. Valuing such non-market impacts is challenging.

We intend to use the subjective wellbeing approach which avoids many of the problems of traditional preference-based approaches. The stated preference method, for example, due to the hypothetical nature of the survey questions, leads individuals to overstate their valuation of a good and also suffers from strategic bias, with individuals deliberately misrepresenting their true preferences (Fujiwara, 2011). The revealed preference method involves important assumptions. In the example above, the revealed preference method requires assuming that housing markets are in equilibrium, that individuals have full information on all house prices and characteristics and that there are zero transaction and moving costs. These assumptions are unlikely to be met (Fujiwara, 2011).

Data sources: We will use the BL neighbourhood-level secondary datasets that are being created as part of Work Package 1, specifically the data obtained from the ONS Annual Population Survey for the period April 2011 to May 2020.

Outcome measures: We will use the four components of subjective wellbeing (life satisfaction, happiness, anxiety and feeling worthwhile) that are being collected as part of the Annual Population Survey since April 2011.

Analysis: Our starting point is the differences-in-differences approach proposed in Work Package 1. However, in this work package we will expand the analysis of the impact of the BL programme on subjective wellbeing to include all four subjective wellbeing measures. Recent research has confirmed that for subjective wellbeing data measured on a Likert scale linear models work just as well as ordered probit or logit models (Dickerson, Hole & Munford, 2014) so we will use linear regression models. We will monetise the obtained impact estimate using estimates of the impact of income on subjective wellbeing from previous research (ONS, 2016). If BL is a successful intervention, we should obtain a positive monetary value, representing the benefits of the intervention.

Second, we will establish the impact of BL on neighbouring communities. These spill-over effects could be positive or negative. For example, BL might lead to improvements in the environment that also increase subjective wellbeing of residents in neighbouring communities. On the other hand, BL could result in redirecting of resources towards BL communities at the cost of neighbouring communities. We will run a differences-in-differences analysis comparing the change in subjective wellbeing in communities surrounding BL areas to the change in subjective wellbeing in matched comparator areas from the set of areas surrounding the matched comparator areas. The same matching techniques as outlined in WP1 will be used to match LSOAs surrounding BL areas to similar LSOAs among the set of LSOAs surrounding the match comparator areas. Again, we will monetise the estimated spill-over effects using estimates of the impact of income on

subjective wellbeing. If the spill-over effects are positive, the estimated monetary value will be added to the benefits in the cost-benefit analysis. If the spill-over effects are negative, their monetary value will be added to the costs of the intervention.

The major part of the costs of B: will be the resources provided by Big Lottery Fund.

We will use financial information provided in progress reports on local plans from BL partnerships and information from LT to obtain an estimate of the costs for the cost-benefit analysis.

However, most BL areas will use additional resources, such as people's time, premises, reduced price materials or equipment provision. For the 15 fieldwork neighbourhoods involved in WP3 we will collect information on these additional resources during interviews with key informants, focusing particularly on the selected Critical Collective Control Episodes in each neighbourhood. We will search for information on costs in documents available through the BL partnership. To estimate the costs of the time volunteered by active residents, we will use data from the survey of partnership members described in WP2. We will also explore the potential of using data from this survey on residents' assessment of the quality of their volunteering experience: where involvement is reported as frustrating, too much work, boring or lonely, volunteers' time input would be valued at a higher rate than if they find the work satisfying, a learning experience, exciting, rewarding, enjoyable or worth it.

Thus, for 15 BL areas we will obtain an estimate of the full costs of the programme for the cost-benefit analysis. For these 15 BL areas we also have baseline characteristics such as socioeconomic deprivation, population health, ethnicity and age profile as well as information from our work on 'typology' of local BL programmes. Therefore, we can develop a model that predicts the full costs of the programme in the remaining BL areas using their baseline characteristics and typology.

Cost-savings to the NHS: Building on the work in WP1, we will estimate the potential costs saved by the NHS through BL's impact on antidepressant prescribing, A&E attendances and hospital attendances for self-harm using drug tariff and national tariff prices.

Data sharing and storage issues

The steps taken to obtain, manage and share data for specific work packages are described in detail above. In this section we consider general issues underpinning our approach to data sharing and storage across the project.

As the study involves multi-site collaboration across universities, this will this have implications for data protection and storage as well as ensuring consistency in ethical

processes. We developed guidelines for the team covering: issues of informed consent in the context of the type of qualitative inquiry we will be doing: ethical issues associated with sharing and disseminating data with BL deliverers and residents and fieldworker safety during phases 1 and 2 and will continue to use these.

As in Phases 1 and 2, we will continue to follow best practice in order to ensure security of all personal and restricted data. Paper-based data, including transcripts of interviews and field notes, will be kept securely in a locked filing cabinet with restricted access. All confidential, restricted and personal data (electronic and digital) will be stored on password-protected computers, laptops and the university servers of our co-investigators. All restricted or personal data will be encrypted on, computers and laptop; as well as, where necessary on digital recorders, USB stick or other data-holding devices. For sharing of restricted and personal data with other required externals (e.g. where transcribers are contracted), we will use a secure file transfer service (such as Box available at Lancaster University) to transfer audios of interviews. Transcribers will be asked to sign a confidentiality agreement (please see annex 6 for a copy of this agreement). Supervisors/managers will ensure that all researchers attend or complete online information security training. Documents and audio files containing identifiable data that are shared to Box will be encrypted. Word documents will be password encrypted. Audio files will be encrypted using 7-zip freely available, open-source software.

All features that would make individuals/areas identifiable will be removed from publications and other research outputs. Still, it may be difficult to ensure complete anonymity of participants within fieldwork sites, due to the small numbers involved and nature of some participants' roles (e.g. as chairs of BL local Partnerships). We have consulted with Local Trust and national delivery partners to set out plans to protect anonymity and to ensure these are acceptable and will discuss these issues with local fieldwork sites as part of our more detailed fieldwork planning. Where anonymity or confidentiality is not possible to fully guarantee the implications of this will be made clear to all participants in written/verbal information prior to the interview taking place and the relevant consent is sought.

Engagement with key stakeholders

Engagement with key stakeholders will run for the duration of the project, building on relationships already developed during phases 1 and 2 of the CiC study.

BL residents and LT have been involved in all aspects of phases 1 and 2 of the CiC study on which this research builds. Through national and local structures for engagement developed during the earlier phases of the study they contributed to fieldwork design; developing research tools; interpreting findings and plans for dissemination. We had regular meetings

with LT, recruited and trained community researchers, involved residents in fieldwork sites and formed a Resident Network (RN) to support public involvement from non-fieldwork sites.

A range of stakeholders are likely to be interested in engaging with the implications of the findings from this research for policies and practice and for future research. Members of the SPHR research team have built up an international network of academics, public health practitioners and members of the public with experience of and/or interest in research on area based interventions, community empowerment and health inequalities. Several members of the research team are also involved in NIHR Collaborations for Leadership in Applied Health Research and Care (CLAHRC), which provide established routes into NHS and local authority public health and mature knowledge exchange platforms.

We will maximise the impact of our engagement by reaching diverse audiences operating within a clear strategic framework whilst also taking ad hoc opportunities for dissemination as they arise. Our audiences include:

- (i) groups involved in BL (LT, their partners, residents in fieldwork areas and the wider networks of BL resident and paid staff in all 150 areas;
- (ii) NHS and public health commissioners and practitioners working nationally and locally;
- (iii) the third sector;
- (iv) academics involved in evaluative research on community empowerment initiatives. Consultations with these groups during phase 2 of CiC shaped our dissemination strategy for this next phase of the research.

We aim to:

- (i) increase awareness of findings from CiC among all audiences;
- (ii) enable NHS and public health practitioners, community activists and funders to utilise learning from the research in a wide range of contexts;
- (iii) encourage evaluators and funders to reflect on new methods for evaluating CE; and
- (v) contribute to enhanced capacity for public involvement in research amongst public health researchers.

Local fieldwork structures for engagement

In the 15 sites where fieldwork takes place, we will work with the already established or where necessary re-establish mechanisms for regular dialogue and exchange with members of partnership boards/steering groups and other residents and workers in the local area as we did with fieldwork areas during phases 1 and 2. We will however be mindful that the

membership of Partnership boards might have changed and that researchers who originally worked with the fieldwork site might be no longer available.

The purpose of this engagement is to ensure that local evidence priorities are acknowledged and integrated into the research where possible, that local knowledge of the neighbourhood and of *BL* informs the fieldwork, that data gathering methods are acceptable. We will also engage members of *BL* area partnerships/steering groups in our fieldwork sites in the interpretation of findings through meetings in local areas and envisage that local steering group/partnership meetings will provide the most appropriate forum for this. As with phases 1 and 2, we will also discuss whether residents and local workers in the new and existing fieldwork areas are interested in contributing to the development of locally relevant outputs for practice.

National level structures

National Local Trust/SPHR Forum

Routine quarterly meetings will be held to support on-going dialogue between the CiC research team and LT in order to ensure openness and transparency through the research process. Other *BL* stakeholders such as partners/reps will be invited to attend routine meetings between LT /SPHR when this is relevant to the focus of the meetings. To support wider communication with *BL* stakeholders CiC team members will attend meetings organised by LT such as delivery partner meetings and rep days in order to share findings, and update reps about the evaluation.

This programme of work will complement any on-going evaluative work being undertaken locally by *BL* area partnerships and nationally by LT and their delivery partners, by focusing explicitly on the evaluation of health inequalities and social determinants of health outcomes. The LT has resources for evaluation during the 10 years of the *BL* programme and has indicated that they would wish to design their research to complement the SPHR evaluation. Close coordination is ensuring no duplication of effort and effective cross-fertilisation of findings and approaches. For example we have avoided sampling BL areas for fieldwork already involved in LT commissioned research.

Public Involvement in Research

Members of the Resident Network discussed phase 3 of the research project and plans for public involvement in a workshop that took place during the development of the funding proposal. Resident Network members' main concern was that that BL residents are already giving up a lot of their own time by being involved in BL so might find it difficult to get have deep levels of involvement in phase 3 of the study. In order to take account of this we plan to offer a range of involvement and engagement opportunities in CiC phase 3:

- (1) Resident Network Advisory Forum which would comprise of 5 members and meet 3 times a year. This group will be involved in overall project governance and individual work packages, shaping the work and the outputs. Advisory Forum members will receive public involvement payments commensurate with the project's public involvement payment policy and have any travel and accommodation expenses paid for.
- (2) One-off pieces of work e.g. developing study information sheets, reviewing presentations and website materials and co-producing outputs. We will be able to offer payments, commensurate with the project's public involvement payment policy.
- (3) Residents in fieldwork areas advising on data collection and discussing emerging findings. This would most likely happen on an as needed basis, during BL partnership meetings or specially convened meetings in the BL area. Where appropriate we will pay for travel expenses.
- (4) Annual Resident Network Workshops: opportunities for learning, development and networking, planned/delivered with LT and residents. We would not make any public involvement payments for attending this workshop as it is a learning and development opportunity. Where funding is available we might be able to cover a small number of travel bursaries.

Three members of the Resident Network took part in a recent workshop, part of which focused on recruitment and consent processes. After reviewing a small number of information sheets and consent forms (the FHM REC template, one from an early phase of CiC and one from a study led by LSHTM) they provided feedback on the importance of language in helping to promote equality between the researcher and the participant and in the researcher's initial approach to the person being clear about the purpose of the research and what the benefit would be to the person taking part. As a result of feedback from the Resident Network members we have made changes to the lay-out and wording of the information sheets and consent forms which we hope will improve their accessibility.

Our approach to involving members of the public in research is based on good practice guidance from INVOLVE. We expect to cover all reasonable expenses incurred by residents through being involved in the research either through their public involvement or as a research participant. This will include all expenses associated with cheapest possible standard class rail travel, bus travel or mileage; subsistence including meals, snacks and refreshments and accommodation if required. Wherever possible, we will book and pay for expenses directly (e.g. by booking travel tickets in advance). If not possible, we will reimburse residents promptly at a later date. Other out of pocket costs may include

childcare, replacement carer costs or personal assistance and this will be costed for and covered on an individual basis.

We recognise that payments (proxy or otherwise) may have implications for tax and National Insurance liability or benefit entitlement where paid to individuals (there are strict limits on the amount of money that people who are in receipt of any welfare benefit can earn whether this is in the form of cash payment or vouchers). There may be repercussions for local relationships if the process and opportunities for getting involvement are not seen to be fair or transparent. Where payment is offered to individuals, we will strongly recommend to residents that anyone who may be receiving state benefits seek advice before accepting any form of payment. We provide access to a specialist advice service on how public involvement fees affect welfare benefit payments for members of the public involved in NIHR research which has been developed by Involve. As well as signposting residents to these sources of written information on earned income and benefits, we will recommend that residents seek expert advice before they get actively involved and will signpost individuals to external sources of support. This is most likely to include Citizen Advice Bureau offices.

A budget has been allocated to public involvement in research and we have well established procedures for making public involvement payments and paying for or refunding travel expenses. RN Advisory Forum members will be supported to identify training and support needs including opportunities for mentoring/buddying with experienced public advisors, codelivering workshops and access to other resources (e.g. CLAHRC NWC intern programme).

Planned Outputs

Our dissemination strategy for phase 3 comprises six elements:

- (1) Maximizing the relevance of outputs by involving the public/BL stakeholders and public health professionals in identifying policy/practice lessons from findings and developing policy/practice outputs;
- (2) Publishing academic papers in high impact journals;
- (3) Delivering diverse communication mechanisms (bulletins/newsletters, social media, blogs) utilizing existing networks in the health system, collaborating universities and beyond to keep stakeholders up to date with progress and events;

- (4) Maintaining a project website 'open to all' hosting downloadable outputs and resources, e.g. practitioner briefings and links to BL's webpages, events and social media platform as mechanisms for disseminating outputs to BL stakeholders;
- (5) Facilitating a network of health practitioners, residents involved in BL and other area based empowerment initiatives and academics, providing virtual and face-to-face activities supporting reflective practice and learning about approaches to community empowerment. We will have some funding to support this network with public health practitioners though the School for Public Health Research but we will apply for other funds to develop it further;
- (6) Presentations at conferences, events and engagement activities hosted by other organisations to increase the study's profile

We anticipate our primary impacts will be a significant contribution to improving the effectiveness of approaches to empowering disadvantaged communities to improve the social determinants of health and health related outcomes.

In addition to a series of academic papers in high impact journals (at least 1 per WP), we will produce policy and practice focused outputs for professionals and community activists by working closely with key national and local stakeholders including: Public Health England's National Adviser on Communities and NHS England; national third sector agencies currently supporting empowerment initiatives - in particular, LT, which has recently launched a national review of community development in the 2020s; and our network of residents engaged in BL and other community empowerment initiatives.

Possible practice focused content include: recommendations on design and implementation of place-based initiatives aimed at enhancing the collective control of residents of disadvantaged areas over action to improve population health and reduce health inequalities. We will provide practical advice, interactive learning resources supporting the use of the neighbourhood datasets developed in WP1, and other resources for residents working to improve their neighbourhoods. Practical research outputs could include: (a) elaboration of what collective control is, how it could be manifest in different contexts and what markers can be used to assess changes in collective control; and (b) possible methods for applying a systems approach to the evaluation of complex place-based empowerment initiatives (acting as a demonstration project). Drawing on our previous PHRP funded evaluation of New Deal for Communities

(http://dx.doi.org/10.17635/lancaster/researchdata/27), we will explore ways of archiving research material: e.g. (i) datasets for all BL neighbourhoods comprising census and other data, plus a user guide for updating time series data in the future; (ii) a guide and documented programming code for deriving the analytical sample and variables from the BL

partnership members survey dataset; and (iii) detailed documentation of our approach to investigating pathways to impact including our innovative work on describing different types of BL programmes; and (iv) key learning points from our experience of different approaches to economic evaluation of community empowerment initiatives.

Ethical issues relevant to this project

As the fieldwork elements of work package 3 will require research activities (repeated interviews and a small number of observations) to take place over a period of time, it will be important for the operationalisation of informed consent to be viewed as a continuous process rather than a one off event, involving a process of negotiation with individuals and/or a site over time. This is defined by Ramcharan and Cutcliffe (2001) as "process consent" and is particularly important where studies have more emergent designs, stakeholder involvement, and a participatory intent. It is also important in studies involving long term engagement, in which participants may over time forget that the researcher is in the setting to collect data (if consent were conceived as a one-off event at the start of research).

Fieldwork will be undertaken by a number of different researchers in a variety of sites in (15 - 20 local areas plus national settings). Some site/context-specific ethical issues may arise during the course of fieldwork. In order to ensure that researchers involved in fieldwork engage routinely and reflexively with ethical issues including informed consent processes we will put in place a number of measures to ensure consistency in approaches taken including regular opportunities to discuss and review ethical issues (including relationships with local areas) and procedures as they arise during the fieldwork in team meetings (agenda item on team meetings) and identifying a senior member of the research team with whom researchers could discuss ethical issues should they arise

More generally, we think the potential for avoiding participants feeling coerced has been and will continue to be addressed by researchers engaging with BL partnerships and individuals in a respectful and professional manner. From our experience in phases 1 and 2 of CiC, the nature of the BL programme which puts residents in charge of decision-making and building on the empowerment of community members means that they have felt able to decline to take part in interviews or other elements of the study on occasions. In phases 1 and 2 of the study, BL partnerships adopted their own locally agreed decision making processes to decide upon the partnerships' involvement with the study as a group (e.g. voting on whether or not the group wishes to take part in the research or not). It is also our view that data obtained from people who feel they have no choice to take part will be less useful than that from people who take part freely and with enthusiasm and so it is in our best interests to ensure that participants do not feel coerced.

Participants might feel over-researched if they are continuously asked to take part in different research studies or if the research activity they agree to participate in is onerous or time-consuming. As part of the early work to select fieldwork areas we worked closely with the national organisation overseeing the BL programme to ensure that areas we approached were not already involved in other research activity. However, it is also made clear during discussions with BL partnerships about their involvement that the 'partnership' is only consenting to the BL area taking part in the research in general terms (e.g. permission for researchers to attend partnership meetings) and that it is up to individual partnership members and other potential participants within BL areas to consent to whether they wish to take part in the research or not as participants. We will remain vigilant to the potential for individuals feeling over researched or coerced. We will ensure that processes described in sections above are adhered to by project researchers including that individuals are reminded of their rights to withdraw or not take part in the first place.

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Appendix 1: CiC study 3 timelines

Gantt Chart – Detailed breakdown of research timetable

Month	1	2 3	4	5	6 7	8	9 1	0 1	1 1	12	13	14 1	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39
WP1 Population Health Impacts	П		Н	\top	Ħ	\top																													\neg	\top	\neg
Preparing datasets, data cleaning & deriving indicators	П		П	T	Ħ	\top																													\neg	\neg	\neg
Update of indicator dataset	П	T	П	T	П	\top	T	\top	\top	T	1																								T	\neg	\neg
hterim analysis	П		П		П																														\Box	\Box	\neg
Final analysis & writing up	П		П		П																																
WP2 Longitudinal Survey	П		П																																	\Box	\neg
Local Trust survey data collection (2 w aves)	П																																		\Box	T	\neg
Data cleaning, analysis & writing up	П		П	Т	П	\top																															
Residential meeting with Local Trust	П		П		П																																\neg
WP3 Fieldwork			П		П																															\Box	
WP3 fieldwork data collection in 15 areas (2 w aves)	П		П																																	\neg	\neg
National stakeholder interviews (2 w aves)	П		П																																		
Content analysis of plan reviews																																					
WP3 fieldwork analysis & writing up							Т	Т																													
WP4 Health economics	П		П		П																															П	
Data collection, cleaning, early analysis	П		П		П																																
Model development																																					
Final analysis & writing up																																					
Public and practitioner engagement																																					
Meetings with Local Trust Forum																																					
Meetings of Resident Network Forum																																					
Annual Resident Network Workshop																																					
Project management & dissemination																																					
Ethics and preparatory work																																					
Meetings for each WP*																																					
Project Management Team face to face meetings																																					
Advisory Group Meetings																																					
Production academic/non-academic outputs																																					
hterim progress reporting 6 monthly																																					
Final analysis and reporting (all WPs)																																					
*hdicative: meetings for individual WPs will be more frequent during periods of activity and less frequent																																					

Fieldwork Documents for the Communities in Control -phase 3 study

Fieldwork component	Activity	Document	Annex No.
WP3	Local fieldwork interviews about CCC episodes	Invitation letterInformation sheetTopic Guide	1
WP3	Local fieldwork interviews providing a systems perspective	Invitation letterInformation sheetTopic Guide	2
WP3	National fieldwork interviews	Invitation letterInformation sheetTopic guide	3
WP3	All local and national fieldwork interviews	Consent form	4
WP3	Observations of Big Local partnership meetings and events	Information sheetObservation template	5
WP3	All local and national fieldwork interviews	Transcriber confidentiality agreement	6





ANNEX 1: LOCAL FIELDWORK - CCE EPISODES

[Invitation letter for CCC episodes Interview]

[Date and address]

Dear [Name],

The Communities in Control study phase 3: invitation to take part in a study

I am a researcher based at Lancaster University and part of a research team exploring whether programmes like Big Local with its focus on collective decision-making have longer term health and wellbeing benefits for residents. I am contacting you to see if you would be interested in taking part in this study. I have enclosed an information sheet that gives more detailed information about the research.

We think it is important to understand how initiatives like the Big Local work in practice. In particular we are carrying out research into Big Local to see whether giving local residents a say in decisions about how the Big Local money should be spent to make changes in their neighbourhood helps to improve the health and wellbeing of residents living in Big Local areas even where improving health might not be the main focus of the Big Local partnership. We are trying to understand how Big Local is working by speaking to people about particular projects, events or actions taken by Big Local partnerships to improve their area for example by developing a pocket park or taking on ownership of a community building.

[Where relevant include the following paragraph] Your name has been given to us by [name of contact] as somebody who has experience and knowledge of Big Local and [name/description of CCC episode] that has happened fairly recently. We would be really interested in hearing about your experiences with [name of CCC episodes] and invite you to take part in an interview for our fieldwork.

If you think you might be interested in taking part please read the information sheet that I have enclosed. This explains why the research is being undertaken and what will be involved. If you are willing to take part, please contact us using the details above. We will then contact you again to arrange a telephone interview at a time that is convenient to you.

If you have any questions about the project, please contact [insert researcher name and contact details].

Yours sincerely,

[Name of researcher]





[Role/organisation]





Participant Information Sheet [CCC episodes]

Communities in Control study – phase 3

We are researchers based at Lancaster University and working on a research study funded by the National Institute for Health Research (NIHR) Public Health Research Programme. We would like to invite you to take part in our study.

What is the study about?

The purpose of this study is to look at the different ways in which residents in Big Local areas work together to improve their neighbourhoods and what helps and does not help this working together. We are also interested in exploring whether programmes like Big Local can help to reduce the inequalities in health that exist between different groups and areas in England. We are doing this by looking at projects, events or actions that have been undertaken by partnerships in 15 Big Local areas.

This is the third phase of a study that began in 2013. It is due to go on until 2021. If you would like to find out more about the study you can visit our website: https://sphr.nihr.ac.uk/health-inequalities/home/https://communitiesincontrol.uk/

Why have I been approached?

You have been approached because you have been involved in a Big Local partnership and/or [name of project] that the Big Local partnership have been working on. We would be interested in hearing about your experiences of being involved in [name of project/event/activity] and your understanding of how it is happening. We are hoping to speak with up to 5 people in your Big Local area.

Do I have to take part?

No. Taking part is voluntary, it's completely up to you to decide whether or not you take part and you will be given information and time to make this decision. Even if you agree to take part, you can change your mind later without having to give a reason why.

What will I be asked to do if I take part?

If you decide you would like to take part:

- You will be contacted by a researcher working on the project to arrange a convenient time and place for the interview to happen
- The interview should last no longer than an hour and may actually take less time than this.
- Even if you have agreed to take part, you can still decide that you don't want to carry on at any stage (even if it is during the interview) without having to give a reason why
- You can also ask to have any data that you have provided withdrawn up to the up to the point at which we begin to analyse the data.

We would like to speak to you again in about 9 months' time so that we can find out how your experiences have changed over time. However, it is up to you whether or not you decide to take part in this second interview. You will only be contacted again if you have given your permission for the researcher to do so. Even if you have given your permission, you can still choose not to take part at a later stage without having to give a reason why.

Ideally we would like to audio record the interview so you will be asked if you agree to this. If you consent to this, when the interviews have been recorded we will send the audio file to a transcriber to produce a typed version of the interview. The transcriber has signed a confidentiality agreement.

Will my data be Identifiable?





We will make the typed version of the interview anonymous by removing your name and replacing it with a code and also by removing and replacing any other features that might be identifiable. Extracts that have been made anonymous in this way might be used with extracts from interviews with other people in reports, presentations and journal articles to highlight key points from the analysis.

However it might still be possible to identify you because of the specific nature of your role (such as your involvement as a chair or member of a steering group/partnership) and this is something that you should be aware of.

There are also some limits to confidentiality: if what is said in the interview makes me think that you, or someone else, is at significant risk of harm, I will have to break confidentiality and speak to the project leader about this. If possible, I will tell you if I have to do this.

Will my data be stored securely?

The data collected for this study will be stored securely and only the researchers conducting this study will have access to this data:

- o All electronic files will be stored on password-protected computers or laptops
- Any paper copies of information you provide such as Word files of the typed version of the interview will be stored in a locked cabinet
- Audio recordings will be destroyed and/or deleted once the project has been submitted for publication
- At the end of the study, any paper copies of information you provide will be kept securely in a locked archive room for ten years. Electronic files will be kept securely in the Lancaster University repository. At the end of this period all files will be destroyed.
- All your personal data (e.g. name, contact details) will be confidential and will be kept separately from your interview responses.

What will happen to the results?

The information you provide in the interview will be combined with information from interviews with other people and will be analysed by the researchers. The findings will be reported in academic journal articles but we will also develop some practical resources for Big Local residents as well as workers and researchers interested in initiatives like Big Local.

With your consent, transcriptions of your interview may be archived for potential use by other researchers in the future. This will only take place if all features that could identify you, other individuals or local areas can be removed so the transcript is completely anonymous.

Are there any risks?

We think that the possibility of risk, discomfort or inconvenience is likely to be low. A potential disadvantage might arise if you feel that you might be identifiable because of the specific nature of your role.

If you experience any distress following the interview you are encouraged to speak with the researcher in order to work out what the best form of support for you might be.

Are there any benefits to taking part?

Although you may find participating interesting, there are no direct benefits in taking part.

Out of pocket expenses and vouchers

We will cover all reasonable expenses that occur as a result of your taking part in this interview (e.g. travel, subsistence, childcare). Where possible we will book and pay for expenses (e.g. travel) directly. Where applicable, the researcher will speak to you about this





process and will give you an expenses form. If you think you will incur expenses other than travel, please let the researcher know this in advance of the interview taking place.

We will also offer a £15 voucher as a 'thank you gift' for residents living in Big Local areas who are invited to participate in the fieldwork interview. This voucher is available for members of the public who are involved in Big Local in a voluntary capacity. It is not being offered to individuals who are formally connected to Big Local (e.g. the BL rep, worker or Locally Trusted Organisation).

Future contact with you

We would like to keep your contact details so that we can get in touch with you again about taking part in another interview in the future or to update you on how the project is going. We many also contact you to ask if you would be willing to participate in a further phase of the research in the future. Your contact details will be stored securely and will not be passed onto anyone else and will be destroyed when the project ends. If you would prefer us not to keep you contact details please tell us.

Who has reviewed the project?

This study has been reviewed and approved by the Faculty of Health and Medicine Research Ethics Committee at Lancaster University.

Where can I obtain further information about the study if I need it?

If you have any questions about the study, please contact the main researcher:

[Name and University contact details of fieldworker undertaking the research]

Complaints

If you wish to make a complaint or raise concerns about any aspect of this study and do not want to speak to the researcher, you can contact the study's Principle Investigator:

Professor Jennie Popay Tel: (01524) 592493 Email: j.popay@lancaster.ac.uk Division of Health Research, Faculty of Health and Medicine, Furness Building, Lancaster University, Lancaster LA1 4YG

If you wish to speak to someone outside of the [name of] Doctorate Programme, you may also contact:

Professor Roger Pickup Tel: +44 (0)1524 593746
Associate Dean for Research Email: r.pickup@lancaster.ac.uk
Faculty of Health and Medicine
(Division of Biomedical and Life Sciences)
Lancaster University
Lancaster
LA1 4YG

Thank you for taking the time to read this information sheet.





For further information about how Lancaster University processes personal data for research purposes and your data rights please visit our webpage: www.lancaster.ac.uk/research/data-protection





Topic Guide for Local fieldwork – CCE episodes

Big Local Area:	Date of interview:
Interviewer initials:	Location ID:
Recorded? Yes/No*	Interviewee ID:
(*reason if not)	
Overall code for interview:	

Prior to Interview.

Introductions:

- Name, role, university
- Purpose of the research
- Research funder emphasise that although we've received permission from Local Trust to conduct the study we are not connected to them and are independent researchers who are receiving funding from NIHR Public Health Research programme

Ethical issues:

- Thank you for agreeing to take part, [check that the participant is still happy to do so and remind of rights to withdraw self from interview and data up to the point of analysis].
- Explain that the researchers may want to approach the participant to take part in a
 follow up interview, however, emphasis that this is completely voluntary. The
 participant would only be approached if they have given permission to be contacted
 again (e.g. on consent form) and the participant can choose not to not take part if
 they prefer not to.
- For repeat interviews, ensure that re-consent process is audio-recorded (read through each consent statement and ask participant to state if they consent/do not consent.
- Check about any out of pocket expenses, explain process provide form if appropriate
- Check whether it's ok to take an audio recording
- Remind about confidentiality
- Material will be anonymised but sometimes because of the specific nature of people's role they might be recognised – please bear this in mind
- You can refuse to answer questions
- We can stop whenever you like
- If you need to take a break please let me know
- Do you have any questions or anything you'd like to clarify?

Sign consent form – keep the form so that it can be scanned and stored digitally. Offer to send the original form by post or a scanned copy by email.

Check recorder is working if using

If participant is taking part in more than one interview:





I won't ask you to sign another form, but I will remind you of your rights (described above) next time we meet.

About the participant and role in Big Local

- Briefly describe role (or relationship) in relation to Big Local (BL)
- Whether involved in initiatives like BL previously
- If resident (or worker as appropriate), how long lived in local area

Understanding the incident

- Please describe your understanding of how [the event] unfolded?
- What was the trigger for [the event]/how did it come about?
- Who was involved/who were the main players?
- What happened?

General impact of incident

- What impact is [the event] having on local residents and other stakeholders in the BL area? Different impacts for different people/groups?
- What impact is [the event] having on BL plans, priorities and activities?
- Any other impacts of [the event]?

Impact on development of collective control

- View on how important it is for local residents to have greater control over things that affect their lives or what happens in this area? If so, why/how (or why not)
- Do they think BL is so far supporting local residents to have greater control? If so, why/how (or why not)
- How has [the event] impacted on resident control (for individuals and the group as a whole)? Has it increased or decreased resident control.
- [more specific questions in relation to different types of control power to, with, within, etc?]

Future reflections

What do you envisage is going to be the long-term impact of the event (if any)?

Post interview de-brief

- Thank you
- Explain what will happen next. If participant has agreed to take part in another interview check that they are still happy to do so and say approximately when you'll next be in touch to arrange the next interview (if a second interview is planned)
- If you'd like to get in touch with me please use the contact details on the sheet

Researcher observations immediately post interview, e.g. any issues affecting interview such as background noise or other salient points that would help their recall for analysis – main impression, tone, something that jumped out for the researcher, something to follow up, and any off recording comments, other relevant factors.





ANNEX 2: LOCAL FIELDWORK - SYSTEMS PERSPECTIVE

[Invitation letter for Local Fieldwork Systems Perspective Interview]

[Date and address]

Dear [Name],

The Communities in Control study phase 3: invitation to take part in a study

I am a researcher based at Lancaster University and part of a research team exploring whether programmes like Big Local with its focus on collective decision-making have longer term health and wellbeing benefits for residents. I am contacting you to see if you would be interested in taking part in this study. I have enclosed an information sheet that gives more detailed information about the research.

We think it is important to understand how initiatives like the Big Local work in practice. In particular we are carrying out research into Big Local to see whether giving local residents a say in decisions about how the Big Local money should be spent to make changes in their neighbourhood helps to improve the health and wellbeing of residents living in Big Local areas even where improving health might not be the main focus of the Big Local partnership. We are trying to understand how Big Local is working by speaking to people about particular projects, events or actions taken by Big Local partnerships to improve their area for example by developing a pocket park or taking on ownership of a community building.

[Where relevant include the following paragraph] Your name has been given to us by [name of contact] as somebody who has experience and knowledge of Big Local in [name of area]. We would like to invite you to take part in an interview for our fieldwork.

If you think you might be interested in taking part please read the information sheet that I have enclosed. This explains why the research is being undertaken and what will be involved. If you are willing to take part, please contact us using the details above. We will then contact you again to arrange a telephone interview at a time that is convenient to you.

If you have any questions about the project, please contact [insert researcher name and contact details].

Yours sincerely,

[Name of researcher]

[Role/organisation]

Participant Information Sheet [Systems Perspective Interview]

Communities in Control study – phase 3





We are researchers based at Lancaster University and working on a research study funded by the National Institute for Health Research (NIHR) Public Health Research Programme. We would like to invite you to take part in our study.

What is the study about?

The purpose of this study is to look at the different ways in which residents in Big Local areas work together to improve their neighbourhoods and what helps and does not help this working together. We are also interested in exploring whether programmes like Big Local can help to reduce the inequalities in health that exist between different groups and areas in England. We are doing this by looking at projects, events or actions that have been undertaken by partnerships in 15 Big Local areas.

This is the third phase of a study that began in 2013. It is due to go on until 2021. If you would like to find out more about the study you can visit our website: http://sphr.nihr.ac.uk/health-inequalities/home/https://communitiesincontrol.uk/

Why have I been approached?

You have been approached because you have been involved in a Big Local partnership or worked with a Big Local partnership. We would be interested in hearing about your experiences of being involved in the work of Big Local and your understanding of what has shaped this work. We are hoping to speak to up to 5 people in the [name of Big Local area].

Do I have to take part?

No. Taking part is voluntary, it's completely up to you to decide whether or not you take part and you will be given information and time to make this decision. Even if you agree to take part, you can change your mind later without having to give a reason why.

What will I be asked to do if I take part?

If you decide you would like to take part:

- You will be contacted by a researcher working on the project to arrange a convenient time and place for the interview to happen
- The interview should last no longer than an hour and may actually take less time than this.
- Even if you have agreed to take part, you can still decide that you don't want to carry on at any stage (even if it is during the interview) without having to give a reason why
- You can also ask to have any data that you have provided withdrawn up to the point at which we start to analyse the data.

We would like to speak to you again in about 9 months' time so that we can find out how your experiences have changed over time. However, it is up to you whether or not you decide to take part in this second interview. You will only be contacted again if you have given your permission for the researcher to do so. Even if you have given your permission, you can still choose not to take part at a later stage without having to give a reason why.

Ideally we would like to audio record the interview so you will be asked if you agree to this. If you consent to this, when the interviews have been recorded we will send the audio file to a transcriber to produce a typed version of the interview. The transcriber has signed a confidentiality agreement.

Will my data be Identifiable?

We will make the typed version of the interview anonymous by removing your name and replacing it with a code and also by removing and replacing any other features that might be identifiable. Extracts that have been made anonymous in this way might be used with





extracts from interviews with other people in reports, presentations and journal articles to highlight key points from the analysis.

However it might still be possible to identify you because of the specific nature of your role (such as your involvement as a chair or member of a steering group/partnership) and this is something that you should be aware of.

There are also some limits to confidentiality: if what is said in the interview makes me think that you, or someone else, is at significant risk of harm, I will have to break confidentiality and speak to a member of staff about this. If possible, I will tell you if I have to do this.

Will my data be stored securely?

The data collected for this study will be stored securely and only the researchers conducting this study will have access to this data:

- o All electronic files will be stored on password-protected computers or laptops
- Any paper copies of information you provide such as Word files of the typed version of the interview will be stored in a locked cabinet
- Audio recordings will be destroyed and/or deleted once the project has been submitted for publication
- At the end of the study, any paper copies of information you provide will be kept securely in a locked archive room for ten years. Electronic files will be kept securely in the Lancaster University repository. At the end of this period all files will be destroyed.
- All your personal data (e.g. name, contact details) will be confidential and will be kept separately from your interview responses.

What will happen to the results?

The information you provide in the interview will be combined with information from interviews with other people and will be analysed by the researchers. The findings will be reported in academic journal articles but we will also develop some practical resources for Big Local residents as well as workers and researchers interested in initiatives like Big Local.

With your consent, transcriptions of your interview may be archived for potential use by other researchers in the future. This will only take place if all features that could identify you, other individuals or local areas can be removed so the transcript is completely anonymous.

Are there any risks?

We think that the possibility of risk, discomfort or inconvenience is likely to be low. A potential disadvantage might arise if you feel that you might be identifiable because of the specific nature of your role.

If you experience any distress following the interview you are encouraged to speak with the researcher in order to work out what the best form of support for you might be.

Are there any benefits to taking part?

Although you may find participating interesting, there are no direct benefits in taking part.

Out of pocket expenses and vouchers

We will cover all reasonable expenses that occur as a result of your taking part in this interview (e.g. travel, subsistence, childcare). Where possible we will book and pay for expenses (e.g. travel) directly. Where applicable, the researcher will speak to you about this process and will give you an expenses form. If you think you will incur expenses other than travel, please let the researcher know this in advance of the interview taking place.





We will also offer a £15 voucher as a 'thank you gift' for residents living in Big Local areas who are invited to participate in the fieldwork interview. This voucher is available for members of the public who are involved in Big Local in a voluntary capacity. It is not being offered to individuals who are formally connected to Big Local (e.g. the BL rep, worker or Locally Trusted Organisation).

Future contact with you

We would like to keep your contact details so that we can get in touch with you again about taking part in another interview in the future or to update you on how the project is going. We many also contract you to ask if you would be willing to participate in a further phase of the research in the future Your contact details will be stored securely, will not be passed onto anyone else and will be destroyed when the project ends. If you would prefer us not to keep you contact details please tell us.

Who has reviewed the project?

This study has been reviewed and approved by the Faculty of Health and Medicine Research Ethics Committee at Lancaster University.

Where can I obtain further information about the study if I need it?

If you have any questions about the study, please contact the main researcher:

[Name and University contact details of fieldworker undertaking the research]

Complaints

If you wish to make a complaint or raise concerns about any aspect of this study and do not want to speak to the researcher, you can contact the study's Principle Investigator:

Professor Jennie Popay Tel: (01524) 592493 Email: j.popay@lancaster.ac.uk Division of Health Research, Faculty of Health and Medicine, Furness Building, Lancaster University, Lancaster LA1 4YG

If you wish to speak to someone outside of the [name of] Doctorate Programme, you may also contact:

Professor Roger Pickup Tel: +44 (0)1524 593746
Associate Dean for Research Email: r.pickup@lancaster.ac.uk
Faculty of Health and Medicine
(Division of Biomedical and Life Sciences)
Lancaster University
Lancaster
LA1 4YG

Thank you for taking the time to read this information sheet.

For further information about how Lancaster University processes personal data for research purposes and your data rights please visit our webpage: www.lancaster.ac.uk/research/data-protection





Topic Guide for local fieldwork - Systems perspective

Big Local Area:	Date of interview:
Interviewer initials:	Location ID:
Recorded? Yes/No*	Interviewee ID:
(*reason if not)	
Overall code for interview:	

Prior to Interview.

Introductions:

- Name, role, university
- Purpose of the research
- Research funder emphasise that although we've received permission from Local Trust to conduct the study we are not connected to them and are independent researchers who are receiving funding from the School for Public Health Research

Ethical issues:

- Thank you for agreeing to take part, [check that the participant is still happy to do so and remind of rights to withdraw self from interview and data up to the point of analysis].
- Check about any out of pocket expenses, explain process provide form if appropriate
- Check whether it's ok to take an audio recording
- Remind about confidentiality
- Material will be anonymised but sometimes because of the specific nature of people's role they might be recognised – please bear this in mind
- You can refuse to answer questions
- We can stop whenever you like
- If you need to take a break please let me know
- Do you have any questions or anything you'd like to clarify?

Sign consent form – keep the form so that it can be scanned and stored digitally. Offer to send the original form by post or a scanned copy by email.

Check recorder is working if using

If participant is taking part in more than one interview:

I won't ask you to sign another form, but I will remind you of your rights (described above) next time we meet.

About the participants and role in Big Local

- Briefly describe roles in relation to Big Local (BL)
- Whether any participants were involved in initiatives like BL previously
- If resident (or worker as appropriate), how long lived in local area





Describing the local area

Ask for views on:

- What the local neighbourhood was like at start of *BL* (e.g. *characteristics such as features of the population, local economy, community facilities etc)*
- What the area is like as a place to live in general (e.g. strengths/challenges)
- What the local area was like in the past (e.g. any major industrial/social change)
- Ask if other similar initiatives like BL in this area before BL started?
- Relationships between local people in general and organisations like Council before BL
- Relationships between residents/different groups of residents in general within area before *BL* (e.g. whether sense of identity, cohesion in area)
- Can you give any examples where BL residents have worked together to directly
 address, or influence decisions about, neighbourhood issues? (Interviewers might
 want to suggest an example if participant seems unsure or the chosen example does
 not generate useful discussion)
 - Tell me what happened, in your own words. (*Prompts to elicit a narrative* how did you first get involved in the issue?)

Probes relating to CCIF system

Social relationships and public sector culture/resources

- Who was involved? How did they come to be involved? Prompt Which residents?
 The Chair, LTO Rep, LT? Local council? (F2, F6, F5)
- 2. How did people work together? *Prompt -* How were decisions made? (F4, F5, F6)
- 3. Since working to address this issue, have you noticed any changes in relationships between local residents?
- 4. Since working to address this issue, have there been any changes in the way residents work with other organisations (councils, schools business, charities?)

Collective control capacity – skills and knowledge

- 5. What skills were important when you were working to address this issue together?
 (F1)
- 6. What skills /knowledge (if any) were developed when you were working together? (F1)

Material resources

7. Which local assets/resources (ie, buildings, green spaces, roads and other local facilities) were needed when working together? (F3)





8. Has this action brought about any changes in local resources/assets? (F3)

External perceptions

- 9. Has this resulted in any changes in how the area is viewed by local residents (e.g. people living or working in this area?) (F7)
- 10. Has this resulted in changes in how the area is viewed by people who are external to the area (e.g. residents of other neighbourhoods or professionals/journalists) (F7)

Other amplifiers and dampeners

- 1. Was there anything that worked really well as part of the process of working together?
- 2. What challenges were there if any when working to address this issue?
- 3. How successful do you think you were in addressing the issue? What makes you say that?

Collective control capacity - confidence

- 1. What do you expect to happen with this neighbourhood issue in the future? (F1)
- 2. What will success look like with this issue? Who will continue to be involved?
- 3. How do you expect future neighbourhood issues will be addressed? (F1)
 - a. Are residents planning to address other issues?
 - b. Is there anything that you would do differently next time?

Other examples

- How typical was this example in terms of your experience of BL?
- Is there anything else that you would like to talk about in relation to these BL activities?

Costs associated with Big Local

Ask about any knowledge of costs associated with Big Local and if documentation available (particularly core workers or members of partnership with most in-depth knowledge)

- Use of buildings for committee meetings, office, public meetings, etc.;
- Subsidies for utilities (council tax, electricity, gas, telephone/ internet);
- Any personnel provided by other organizations for activities
- Subsidies for office materials;
- Provision of meals / refreshments;
- Training provided without cost.





Future plans

• What will be happening over the next 12-18 months – key milestones

Researcher observations immediately post interview, e.g. any issues affecting interview such as background noise or other salient points that would help their recall for analysis – main impression, tone, something that jumped out for the researcher, something to follow up, and any off recording comments, other relevant factors.





ANNEX 3: NATIONAL FIELDWORK

[Invitation letter for National Fieldwork Interview]

[Date and address]

Dear [Name],

The Communities in Control study phase 3: invitation to take part in a study

I am a researcher based at Lancaster University and part of a research team exploring how taking part in Big Local affects people's health and wellbeing. I am contacting you to see if you would be interested in taking part in this study. I have enclosed an information sheet that gives more detailed information about the study. If you would like to find out more about what we did in phases 1 and 2 of the study you can visit the project's website: http://sphr.nihr.ac.uk/health-inequalities/home/

We think it is important to understand how initiatives like the Big Local work in practice. In particular we are interested in finding out about factors affecting the process of Big Local delivery, adaptations to the Big Local programme over time and how Big Local might affect the way residents work together in a neighbourhood and its impact on health inequalities.

[Where relevant include the following paragraph] Your name has been given to us by [name of contact] as somebody who has experience and knowledge of Big Local either as a Local Trust employee or a delivery partner. We would like to invite you to take part in an interview for our fieldwork.

If you are interested in taking part please read the information sheet that I have enclosed. This explains why the research is being undertaken and what will be involved. If you are willing to take part, please contact us using the details above. We will then contact you again to arrange a telephone interview at a time that is convenient to you.

If you have any questions about the project, please contact [insert researcher name and contact details]. Yours sincerely,

[Name of researcher]

[Role/organisation]







Participant Information Sheet [national fieldwork]

Communities in Control study – phase 3

We are researchers based at Lancaster University and working on a research study funded by the National Institute for Health Research (NIHR) Public Health Research Programme. We would like to invite you to take part in our study.

What is the study about?

The purpose of this study is to look at the health-related impacts of initiatives like Big Local that seek to increase the control communities have over making improvement to their neighbourhoods. We also intend to explore what helps or impedes collective decision-making at the local level. This is the third phase of a study that began in 2013. It is due to go on until 2021. If you would like to find out more about the study and its earlier findings you can visit our website: https://communitiesincontrol.uk/

Why have I been approached?

You have been approached because you have been involved in the Big Local programme. We would be interested in hearing about your perceptions of local and national-level barriers and enablers to collective decision-making in the context of Big Local. We would also like to draw on your professional experience in exploring how collective decision-making might impact on residents' health and well-being. We are hoping to speak to up to 8 people who have been involved with the Big Local programme.

Do I have to take part?

No. Taking part is voluntary, it's completely up to you to decide whether or not you take part and you will be given information and time to make this decision. Even if you agree to take part, you can change your mind later without having to give a reason why.

What will I be asked to do if I take part?

If you decide you would like to take part:

- You will be contacted by a researcher working on the project to arrange a convenient time and place for the interview to happen
- The interview should last no longer than an hour and may actually take less time than this.
- Even if you have agreed to take part, you can still decide that you don't want to carry on at any stage (even if it is during the interview) without having to give a reason why
- You can also ask to have any data that you have provided withdrawn up to the point at which we begin to analyse the data.

Ideally we would like to audio record the interview so you will be asked if you agree to this. If you consent to this, when the interviews have been recorded we will send the audio file to a transcriber to produce a typed version of the interview. The transcriber has signed a confidentiality agreement.

Will my data be Identifiable?

We will make the typed version of the interview anonymous by removing your name and replacing it with a code and also by removing and replacing any other features that might be identifiable. Extracts

that have been made anonymous in this way might be used with extracts from interviews with other people in reports, presentations and journal articles to highlight key points from the analysis.

However it might still be possible to identify you because of the specific nature of your role. We might also have been introduced to you or been recommended to speak to you by Local Trust staff members. This is something that you should be aware of. If you have any concerns please discuss these with the researcher.





NHS
National Institute for
Health Research

There are also some limits to

confidentiality: if what is said in the interview makes me think that you, or someone else, is at significant risk of harm, I will have to break confidentiality and speak to a member of staff about this. If possible, I will tell you if I have to do this.

Will my data be stored securely?

The data collected for this study will be stored securely and only the researchers conducting this study will have access to this data:

- All electronic files will be stored on password-protected computers or laptops
- Any paper copies of information you provide such as Word files of the typed version of the interview will be stored in a locked cabinet
- Audio recordings will be destroyed and/or deleted once the project has been submitted for publication
- At the end of the study, any paper copies of information you provide will be kept securely in a locked archive room for ten years. At the end of this period, they will be destroyed.
- All your personal data (e.g. name, contact details) will be confidential and will be kept separately from your interview responses.

What will happen to the results?

The information you provide in the interview will be combined with information from interviews with other people and will be analysed by the researchers. The findings will be reported in academic journal articles but we will also develop some practical resources for Big Local residents as well as workers and researchers interested in initiatives like Big Local.

With your consent, transcriptions of your interview may be archived for potential use by other researchers in the future. This will only take place if all features that could identify you, other individuals or local areas can be removed so the transcript is completely anonymous.

Are there any risks?

We think that the possibility of risk, discomfort or inconvenience is likely to be low. A potential disadvantage might arise if you feel that you might be identifiable because of the specific nature of your role.

If you experience any distress following the interview you are encouraged to speak with the researcher in order to work out what the best form of support for you might be.

Are there any benefits to taking part?

Although you may find participating interesting, there are no direct benefits in taking part.

Out of pocket expenses and vouchers

We will cover all reasonable expenses that occur as a result of your taking part in this interview (e.g. travel, subsistence, childcare). If you think you will incur expenses other than travel, please let the researcher know this in advance of the interview taking place.

Future contact with you

We would like to keep your contact details so that we can get in touch with you again to update you on how the project is going. We may also contact you about a further phase of the research in the future. Your contact details will be stored securely and will not be passed onto anyone else and will be destroyed when the project ends. If you would prefer us not to keep you contact details please tell us.

Who has reviewed the project?

This study has been reviewed and approved by the Faculty of Health and Medicine Research Ethics Committee at Lancaster University.





NHS National Institute for Health Research

Where can I obtain further

information about the study if I need it?

If you have any questions about the study, please contact the main researcher:

[Name and University contact details of fieldworker undertaking the research]

Complaints

If you wish to make a complaint or raise concerns about any aspect of this study and do not want to speak to the researcher, you can contact the study's Principle Investigator:

Professor Jennie Popay Tel: (01524) 592493 Email: j.popay@lancaster.ac.uk Division of Health Research, Faculty of Health and Medicine, Furness Building, Lancaster University, Lancaster LA1 4YG

If you wish to speak to someone outside of the [name of] Doctorate Programme, you may also contact:

Professor Roger Pickup Tel: +44 (0)1524 593746
Associate Dean for Research Email: r.pickup@lancaster.ac.uk
Faculty of Health and Medicine
(Division of Biomedical and Life Sciences)
Lancaster University
Lancaster
LA1 4YG

Thank you for taking the time to read this information sheet.

For further information about how Lancaster University processes personal data for research purposes and your data rights please visit our webpage: www.lancaster.ac.uk/research/data-protection







Topic guide - national fieldwork

Big Local Area:	Date of interview:
Interviewer initials:	Location ID:
Recorded? Yes/No*	Interviewee ID:
(*reason if not)	
Overall code for interview:	

Prior to Interview.

Introductions:

- Name, role, university
- Purpose of the research
- Research funder emphasise that although we've received permission from Local Trust to conduct the study we are not connected to them and are independent researchers who are receiving funding from NIHR Public Health Research programme

Ethical issues:

- Thank you for agreeing to take part, [check that the participant is still happy to do so and remind of rights to withdraw self from interview and data up the point of analysis].
- Explain that the researchers may want to approach the participant to take part in a follow up interview, however, emphasis that this is completely voluntary. The participant would only be approached if they have given permission to be contacted again (e.g. on consent form) and the participant can choose not to not take part if they prefer not to.
- For repeat interviews, ensure that re-consent process is audio-recorded (read through each consent statement and ask participant to state if they consent/do not consent.
- Check about any out of pocket expenses, explain process provide form if appropriate
- Check whether it's ok to take an audio recording
- Remind about confidentiality
- Material will be anonymised but sometimes because of the specific nature of people's role they
 might be recognised please bear this in mind
- You can refuse to answer questions
- We can stop whenever you like
- If you need to take a break please let me know
- Do you have any questions or anything you'd like to clarify?

Sign consent form – keep the form so that it can be scanned and stored digitally. Offer to send the original form by post or a scanned copy by email.

Check recorder is working if using

Guide for national level interviews – Communities in Control study





NHS National Institute for Health Research

Respondent's role

- Could you briefly explain your role (and your organisation's role) in relation to Big Local (BL)?
- How long have you/your organisation been involved with BL, and why did you become involved originally?
- Can you tell me about the types of support that your organisation provides to local areas (e.g. specific initiatives?)

Aspirations and change

- What are your aspirations for the BL programme? Have they changed over time?
- What do you understand by residents having 'control' at the collective or community level in the context of BL?

Prompts:

- Examples of how BL residents working together to directly address, or influence decisions about, neighbourhood issues?
- What types of skills /capabilities are residents developing from involvement in Big Local?
- Are there any changes that have happened nationally because of Big Local?

Social determinants and Health inequalities

- What sorts of health inequalities do you think residents of local areas are facing? Has this changed since BL started?
- As a result of Big Local, have you observed any changes in:
 - relationships between local residents?
 - in the way residents work with other organisations (councils)
 - how other organisations engage/collaborate with residents
 - physical environments and local assets/resources
 - local economy (e.g. employment, enterprise)
 - how the area is viewed by residents / externally
 - To what extent do you think that BL can influence health or wellbeing of residents living in BL areas?

Prompts:

- Individual residents involved
- Local populations
- Positive or negative impacts
- How do you think BL will influence health in this way? If no, why not?

Intervention e.g. Big Local programme

 What do you see as the core elements of how the BL programme is delivered that are helping to deliver these changes?

Prompts:

- National level support
- Role of reps/local support
- Other support available





NHS National Institute for Health Research

•In what ways is the BL

programme similar or different to other neighbourhood initiatives that you know about or have worked on in this respect?

 How important do you think the funding/investment is in itself in terms of increasing residents' control?

Context

- Are there factors that have helped to enable change to happen within local neighbourhoods?
 What kind of factors within local neighbourhoods are barriers?
- Prompt
- Geographical boundaries of BL
- Relationships between residents
- · Relationships with agencies
- Austerity measures

Thinking about how Big Local functions at the national level:

- What factors that enable the programme in achieving its longer-term aspirations? What challenges are there in how Big Local operates nationally? Are there any new potential challenges on the horizon to Big Local
- Are there aspects of Big Local's model that you hope will provide learning for other organisations / contexts about how communities are involved/influence decision making?

Closing interview

- Ask if any further comments/reflections from participant
- Ask if any events/meetings over next few months that would be possible for us to observe
- Follow up if documents/info mentioned in interview

Post interview de-brief

Thanks

Explain what will happen next.

Researcher observations immediately post interview, e.g. any issues affecting interview such as background noise or other salient points that would help their recall for analysis – main impression, tone, something that jumped out for the researcher, something to follow up, and any off recording comments, other relevant factors.







ANNEX 4: CONSENT FORM FOR ALL INTERVIEWS

Consent Form

Study Title: Communities in Control study - phase 3

We are asking if you would like to participate in a research project exploring how taking part in Big Local affects people's health and wellbeing. If you have any questions before signing the consent form please speak to [researcher's name].

Before you decide whether to take part in the study please read the participant information sheet and mark each statement with either a yes or no	Please circle delete as appropriate
I have read and understood the information sheet	Yes / No
I have had an opportunity to ask any questions and have them answered to my satisfaction	Yes / No
I give my permission for the interview to be audio recorded and then made into an anonymised typed document	Yes / No
I give my permission for audio recordings to be kept until the research project has been published	Yes / No
I understand that my taking part in the study is voluntary and that I am free to withdraw at any time without giving any reason	Yes / No
I understand that once my data have been anonymised and incorporated into themes it might not be possible for it to be withdrawn, though every attempt will be made to remove my data, up to the point at which the data analysis begins	Yes / No
I give my permission for information from my interview to be pooled with other participants' responses, anonymised and where applicable to be published	Yes / No
I give my permission for information and quotations from my interview to be used in reports, conferences and training events	Yes / No







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I give my permission for information and quotations from my interview to be used in reports, conferences and training events	Yes / No
I understand that any information I give will remain anonymous unless there appears to be a risk of harm to myself or others, in which case the researcher will need to share this information with the project's lead	Yes / No
I give my consent for my contact details to be retained so I may be contacted about a further phase of the research at some point in the future.	Yes / No
I give my permission for Lancaster University to keep written transcriptions of the interview for 10 years after the study has finished	Yes / No
I consent to take part in the above study	Yes / No

PARTICIPANT

Signed Print name
Date
Printed name
RESEARCHER I have explained the study to the above participant and they have indicated their willingness to take part.
Signed Print name
Date
Printed name

Consent form to be scanned saved for digital archiving - original document to be returned to the participant by post or a scanned copy by email.







ANNEX 5: OBSERVATION OF BIG LOCAL PARTNERSHIP MEETINGS AND EVENTS

Participant Information Sheet

Communities in Control study - phase 3

We are researchers based at Lancaster University and working on a research study funded by the National Institute for Health Research (NIHR) Public Health Research Programme. We would like to let you know about our research study into Big Local which involves observing meetings like this. We have provided information (below) to help you understand why the study is being carried out and what it involves. Please ask us (using the contact details below or by speaking to the researcher present at [activity]) if there is anything that is not clear.

What is the study about?

The purpose of this study is to look at the different ways in which residents in Big Local areas work together to improve their neighbourhoods and what helps and does not help this working together. We are also interested in exploring whether programmes like Big Local can help to reduce the inequalities in health that exist between different groups and areas in England. We are doing this by looking at projects, events or actions that have been undertaken by partnerships in 15 Big Local areas.

This is the third phase of a study that began in 2013. It is due to go on until 2021. If you would like to find out more about the study you can visit our website: http://sphr.nihr.ac.uk/health-inequalities/home/

Why is this meeting being observed?

We are trying to understand how Big Local is working in your area by interviewing people who have experience and knowledge about how it is being rolled out and also by observing meetings like this which is likely to help us to better understand how Big Local is being implemented.

The organiser of this event has agreed that we can observe it and take notes.

What will happen during the observation?

A researcher will observe and might take notes about what is happening during the meeting. The notes will not contain any information that means that individuals could be identified, but we might be interested in making a note of what people do as part of their role (e.g. as chair of a meeting). No one will be directly quoted when we write up our findings, unless they are speaking in a public capacity.

Information from the notes might be used, along with interview transcripts and documentary analysis to form part of our analysis of how Big Local is working in your area.

What will be observed?

There are a number of things that the researcher might be interested in observing including:

- numbers of people attending [the activity]
- how people interact with each other
- how information is communicated
- how decisions are made







what kinds of resources are available and how they are used

What are the possible disadvantages and risks of taking part?

We think that the possibility of risk, discomfort or inconvenience is likely to be low. A potential disadvantage might arise if you feel that you might be identifiable because of the specific nature of your role (see point 8 below).

What are the potential benefits of taking part?

In general terms we do not expect the research to have direct benefits for you. We expect the research might provide opportunities for you to develop new skills or relationships during your engagement with the project.

Will my taking part in this study be kept confidential?

We would like to make notes about what happens during meeting but we will remove all identifiable information (e.g. names) from the notes. However it might still be possible to identify some respondents because of the specific nature of their role (such as their involvement as a chair or member of a steering group/partnership) and this is something that you should be aware of.

There are some limits to confidentiality. If what is seen in the observation makes us think that you or someone else is at risk of harm, we will have to break confidentiality and speak to the project's lead about this. If possible, we will tell you if we have to do this.

Will data from this observation be stored securely?

The data collected for this study will be stored securely and only the researchers conducting this study will have access to this data:

- All electronic files (e.g. typed up notes) will be stored on password-protected computers or laptops
- Any paper copies of information from the observation of this meeting (e.g. written notes) will be stored securely in locked cabinets
- At the end of the study, any paper copies of information will be kept securely in a locked archive room for ten years. At the end of this period, they will be destroyed.

What will happen to the results?

We will use the information gathered in this study to develop some practical resources for local residents as well as workers and researchers interested in initiatives like Big Local. We would like to work with residents to develop these resources.

With your consent, notes of the meeting might be archived for potential use by other researchers in the future. This will only take place if all features that could identify you, other individuals or local areas can be removed so the notes are completely anonymous.

Who has reviewed the project?

This study has been reviewed and approved by the Faculty of Health and Medicine Research Ethics Committee at Lancaster University.

Where can I obtain further information about the study if I need it?

If you have any questions about the study, please contact the main researcher:

[Name and University contact details of fieldworker undertaking the research]







Complaints

If you wish to make a complaint or raise concerns about any aspect of this study and do not want to speak to the researcher, you can contact the study's Principle Investigator:

Professor Jennie Popay Tel: (01524) 592493 Email: j.popay@lancaster.ac.uk Division of Health Research, Faculty of Health and Medicine, Furness Building, Lancaster University, Lancaster LA1 4YG

If you wish to speak to someone outside of the [name of] Doctorate Programme, you may also contact:

Professor Roger Pickup Tel: +44 (0)1524 593746
Associate Dean for Research Email: r.pickup@lancaster.ac.uk
Faculty of Health and Medicine
(Division of Biomedical and Life Sciences)
Lancaster University
Lancaster
LA1 4YG

Thank you for taking the time to read this information sheet.

For further information about how Lancaster University processes personal data for research purposes and your data rights please visit our webpage: www.lancaster.ac.uk/research/data-protection







Big Local partnership meetings observation template

General information
Time & Date:
Location:
Researcher(s) present:
Nature and purpose of event/meeting (regular steering group meeting, one-off event)
Others present (overview of number of people present, age, gender, ethnicity, role in BL)
If a regular meeting, are there any changes to attendance (e.g. new members)
Any other information to set the scene (e.g. room/location, the way it has been laid out)
Prompts/reminders
PERCEPTIONS OF AREA
COMMUNITY
LOCAL CONTEXT (PHYSICAL, POLITICAL, ECONOMIC ETC)
OTHER INITIATIVES – WHAT IS THE RELEVANCE TO BL.
STAKEHOLDERS ROLES/RELATIONSHIPS







(CHANGES TO PARTNERSHIP, TASK GROUPS, WORKERS)
BL PLAN AND PRIORITIES DISCUSSED (E.G. ACTIVITIES OR IDEAS FOR PLANS)
HOW ARE KEY DECISIONS NEGOTIATED/WHO MAKES DECISIONS?
COMMUNITY INVOLVEMENT
THINGS MENTIONED THOUGHT TO BE AFFECTING CHANGE/PROGRESS (+OR -)
HOW 'RESOURCES' AND ASSETS IN NEIGHBOURHOOD ARE CHANGING AS RESULT OF BL?
Researcher reflections and thoughts on interactions, dynamics, communications
Things to follow up







ANNEX 6: TRANSCRIBER CONFIDENTIALITY AGREEMENT

Confidentiality agreement for transcribers

Name of Study:	Communities in Control – phase 3
Study Researcher:	[name of researcher]

As a transcriber of this research, I understand that I will be hearing recordings of confidential interviews. The information on these recordings has been revealed by interviewees who agreed to participate in this research on the condition that their interviews would remain strictly confidential. I understand that I have a responsibility to honour this confidentially agreement.

I agree not to share any information on these recordings, about any party, with anyone except the researcher of this project. Any violation of this and the terms detailed below would constitute a serious breach of ethical standards and I confirm that I will adhere to the agreement in full.

By signing this document, I agree to

1.	Keep all the research information shared with me confidential by	
	not discussing or sharing the content of the interviews in any form or format (e.g. MP3 files, transcripts) with anyone other than the researcher.	
2.	Keep all research information in any form or format (e.g. MP3 files, transcripts) secure while it is in my possession, e.g. stored on password – protected computers	
3.	Encrypt all files that might have identifying information when returning them to the researcher by password-protecting Word files and using encryption software such as 7-zip for audio files.	
4.	Return all research information in any form or format (e.g. MP3 files, transcripts) to the researcher when I have completed the transcription tasks	
5.	After consulting with the researcher, erase or destroy all research information in any form or format regarding this research project that is not returnable to the researcher (e.g. information stored on my computer hard drive).	
Transcri	ber:	
Signed		.Date







Printed	
name	
Researcher:	
Signed	Date
Printed	
name	