






BMJ Open Different Approaches to requesting Consent for Routine data linkage in Neonatal follow-up (ACORN): protocol for a 2×2 factorial randomised trial

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ABSTRACT

Introduction Routinely collected data can be linked to research data to create a rich dataset and inform practice. However, consent is normally required to link identifiable data. Reported rates of consent to data linkage for children ranged from 21% to 96%, but no studies have investigated different approaches to seeking consent for data linkage for school-age children.

Methods and analysis The Approaches to Consent for Routine Data Linkage in Neonatal Follow-up (ACORN) trial is a 2×2 factorial randomised trial to assess whether, for children who participated in neonatal randomised trials (pre-hypoglycaemia Prevention with Oral Dextrose Gel (hPOD), hPOD and The Impact of Protein Intravenous Nutrition on Development in Extremely Low Birth Weight Babies (ProVIDe)) and are approached to participate in an in-person assessment at 6–7 years of age, parental consent to data linkage is higher if consent is sought (1) after the in-person assessment (delayed) or concurrently and (2) for health and education data combined or separately. The primary outcomes will be rates of consent to linkage of (1) either health or education data and (2) both health and education data. A pilot study indicates the potentially available cohort size of 2110 (80% follow-up of the neonatal trial cohorts) would be adequate to detect an absolute difference of 6%–5%–4% from a baseline consent rate of 70%–85%–90%, respectively (2-tailed alpha 0.05, 90% power). With at least 1136 participants, the ACORN trial would have 90% power to detect an absolute difference of 5% in the primary outcome for each factor, assuming a consent rate of 90% in the control groups and alpha 0.05. Data are categorical and will be presented as number and per cent. The effects of factors will be tested using generalised linear models and presented as ORs and 95% CIs.

Ethics and dissemination Ethics approval by the New Zealand Health and Disability Ethics Committee (19/STH/202). Dissemination will be via peer-reviewed publications, scientific meetings, educational sessions and public fora.

Trial registration number ACTRN12621000571875 (Australian New Zealand Clinical Trials Registry).

INTRODUCTION

Events and interventions around the time of birth can have significant long-term impact on a child's health and well-being.^{1–2}

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ The Approaches to Consent for Routine Data Linkage in Neonatal Follow-up (ACORN) trial will investigate different approaches to consent for data linkage in a school-age population, using a randomised trial design.
- ⇒ The ACORN trial is adequately powered to detect meaningful differences between the tested approaches to seeking consent for data linkage, but power will be limited for some subgroup analyses.
- ⇒ Participation in the ACORN trial is not explicit; therefore, participants are unaware of their participation.
- ⇒ The ACORN trial is single blind as those requesting consent are aware of participants' allocation group. However, this is unlikely to influence outcomes.

Interventions at this early stage are increasingly being recognised as an effective way of improving life-long health. This requires long-term follow-up of neonates from clinical trials to determine efficacy and safety, and support uptake of interventions.^{3–8} However, follow-up studies are expensive and resource intensive.⁹ Specialised equipment and staff are often required, and these studies can place considerable burden on the participants and their families due to time and travel demands. This can result in reduced participation by families, especially those with limited resources, and risks not achieving representative outcome cohorts.

Some of this burden can be reduced by linking trial data to routinely collected health, education and other government data,¹⁰ allowing assessment of outcomes that would otherwise be time-consuming, costly or impossible to obtain. Linkage to administrative data can give information on participants lost to clinical follow-up, help complete missing data, give opportunity for validation studies, increase the population sample and

allow for the adjustment of multiple variables.¹¹ As a result, data linkage in medical and health fields is also becoming increasingly popular among researchers, practitioners and policy-makers.¹²

When linking different datasets, it is important to ensure participant privacy and safety. With some exceptions in some countries, use of identifiable data usually requires informed consent from the participants. In New Zealand, data are considered a taonga (something sacred, precious or significant)¹³ and health data are subject to National Ethical Standards¹⁴ and Health Information Standards of Governance and Security.^{15 16} Consent from participants or a waiver from an ethics committee is not required for deidentified data, but care must be taken to ensure the risks of identification are minimised. For follow-up studies, the data are not only identifiable but also linked between different sources that were collected separately for different purposes, so informed consent from the participants is required.

Informed consent to data linkage usually must be sought from each participant, or in the case of studies with children, their parents/caregivers. However, if the rates of consent are not high, bias may be introduced as participants who do not consent to data linkage may be systematically different from those who do consent,^{17 18} particularly in cohorts of school-age children, low socioeconomic status, indigenous populations or ethnic minorities.^{19–21} This bias may have an impact on the generalisability of the findings, reducing the potential value of the data.

Little is known about how best to seek consent to data linkage. Berry *et al*²¹ and Kim *et al*²² investigated opt-in versus opt-out consent to linkage of childhood immunisation data to hospital records and sharing of electronic health records and biospecimen data with researchers, respectively. Both studies found substantially higher rates of consent in the opt-out group compared with the opt-in group. Sala *et al*²³ and Sakshaug *et al*²⁴ investigated factors such as wording and placement of the consent question, as well as interviewer characteristics and timing of when to ask for consent in a long-term study. These studies showed that factors such as question format (dependent/independent questions) and placement of the consent question can influence the rates of consent, but also referred to the scarcity of research in this field.

Al Baghal¹⁹ investigated survey factors that influenced participants' consent to data linkage in The United Kingdom Longitudinal Household Study. Investigators sought consent from mothers to link their child's health and education records to the survey and found that 59.4% of mothers consented to both health and education data linkage, and 11.4% said yes to one but no to the other. Consent rates were higher for education data than health data. This may suggest that participants have differing views regarding health and education data, potentially influencing rates of consent depending on whether consent for health and education data is requested as one combined request, or two separate requests. However, this requires further investigation.

These studies suggest that survey factors can have a substantial influence on rates of consent. However, there is little research on best methods of seeking consent for data linkage in adult populations, less in school-age children and none in a New Zealand context. The need to obtain consent for linkage of children's data from parents/caregivers adds a layer of complexity, and little is known on how this is best done, or which factors may influence rates of consent.

We are undertaking the Approaches to Consent for Routine Data Linkage in Neonatal Follow-up (ACORN) trial to determine whether at 6–7 years of age the proportion of children for whom parents/caregivers agree to future data linkage (up to 16 years of age) is influenced by whether: (1) consent is sought concurrently with, or after, an in-person assessment; and (2) consent for health and education data is sought separately or combined. This ACORN trial was registered with the Australian and New Zealand Clinical Trials Registry on 17 May 2021 (ACTRN12621000571875).

METHODS

Study design

The ACORN trial is a substudy within the Neonatal Nutritional Intervention Early School-age Outcomes Studies (NIEOS) longitudinal cohort. NIEOS is assessing the neurocognitive and cardiometabolic function at 6–7 years' corrected age of children from three neonatal trials: pre-hypoglycaemia Prevention with Oral Dextrose Gel (hPOD) and hPOD^{25 26} and The Impact of Protein Intravenous Nutrition on Development in Extremely Low Birth Weight Babies (ProVIDE).²⁷ Along with the early school-age assessment, to better inform clinical practice, access to routine health data (hospital and general practice visits and medications) and education data (school progress and additional support) is being sought. These routine data are available from either the Statistics New Zealand Integrated Data Infrastructure or directly from the Ministry of Health and the Ministry of Education. To access these routine data and link them to the trial data, informed consent is required from the parents/caregivers of these children. All surviving children who took part in the pre-hPOD, hPOD or ProVIDE trials in New Zealand and are able to be contacted to seek consent for the NIEOS study will be eligible for the ACORN trial.

The ACORN trial will assess two approaches to consent for data linkage using a 2×2 factorial randomised trial design. Participants will be randomised to be asked for consent to data linkage either at time of consenting to in-person follow-up assessment (concurrent), or after the in-person assessment (delayed). When participants are asked for consent to data linkage, they will be further randomised to be asked for either consent to linkage of health and education data together (combined), where participants can select yes/no to linkage of health and education data as a single question, or for consent to linkage of health data and education data separately,

Table 1 Factorial design of the ACORN trial.

Factor 1	Delayed consent (intervention)	Concurrent consent (control condition)
Factor 2		
Combined consent (intervention)	Delayed, combined consent	Concurrent, combined consent
Separate consent (control condition)	Delayed, separate consent	Concurrent, separate consent

where participants can select yes/no for health data, and for education data, as separate questions (table 1).

Recruitment

Recruitment commenced on 1 June 2021 and will continue until the desired sample size is reached for each study factor, or when NIEOS recruitment is complete (expected 2027). This study will be carried out in community settings where parents/caregivers of the children are approached for consent to the in-person NIEOS assessments. Consent to participate in the NIEOS assessment is sought by the study coordinator who will send each family a Participant Information Sheet and Consent (PISC) form with an invitation letter to participate in NIEOS by post or email when the child approaches 6 years' corrected age. If they do not hear back within 2–3 weeks, the study coordinator will phone to confirm that the information has been received and to discuss the NIEOS study with parents/caregivers. If the study coordinator is unable to make contact, they will trace participants via alternative contacts. The data linkage consent form is included as part of the PISC form, and can be completed in hard copy

or online, unless the child is randomised to the delayed consent factor. In this case, the parents/caregivers will be sent the information sheet and consent form for data linkage when the letter summarising the findings of the in-person assessment is sent to them (figure 1).

Interventions

The trial will be performed by the study coordinators who seek consent from the parents/caregivers of the children prior to the in-person assessment. It is usual for researchers to seek consent for all aspects of participation in a study at the same time and to provide options for participants to consent to or decline some aspects of the study rather than having to agree to or decline all components of the study as a whole. Therefore, concurrent and separate consent are considered the control conditions. Seeking consent as a combined question may reduce some of the burden of decision-making and encourage consent to linkage of both datasets. Seeking consent after children has completed the in-person assessment, when participants may have a better understanding of the study goals and have built some relationship with the study staff,

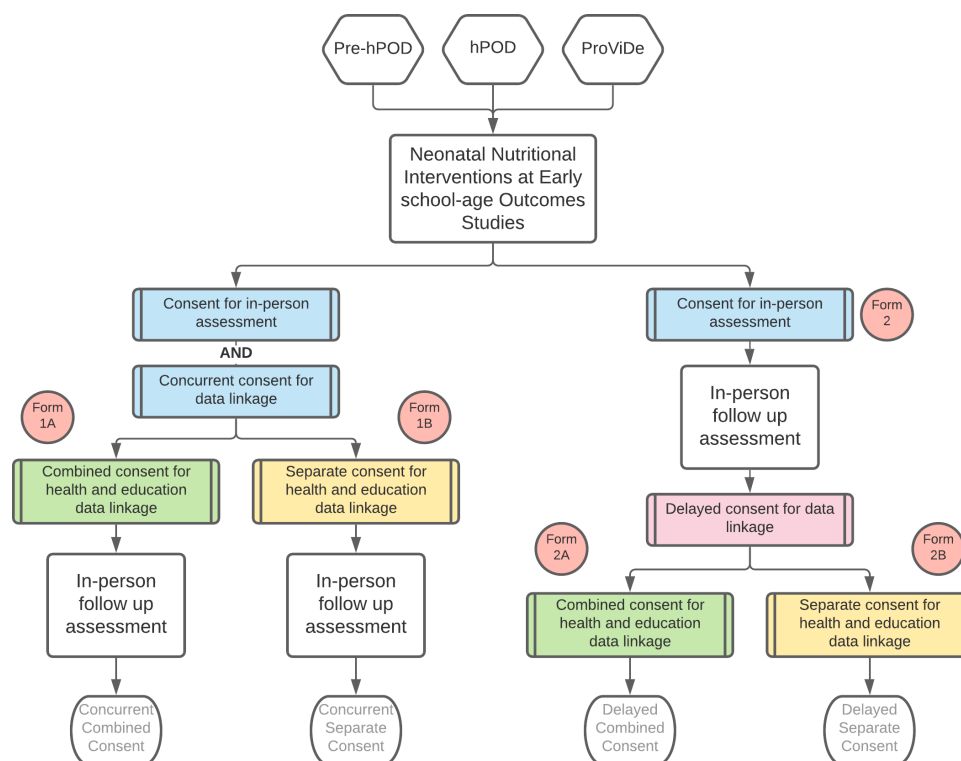


Figure 1 Flow diagram of allocation to factors and timing of consent in relation to in-person follow-up. hPOD, hypoglycaemia Prevention with Oral Dextrose Gel; ProViDe, The Impact of Protein Intravenous Nutrition on Development in Extremely Low Birth Weight Babies.

may encourage consent to the data linkage component of the study. Therefore, delayed and combined consent are considered the treatment conditions.

Factor 1: concurrent versus delayed consent

Concurrent consent

Consent to data linkage will be requested at the same time as consent to the in-person follow-up assessment. Information about data linkage will be included on the PISC form 1A or 1B.

Delayed consent

Consent to data linkage will be requested after the in-person follow-up assessment. At the time of the in-person assessment, PISC form 2, which does not include any information about data linkage, will be used for consent to the assessment. After the assessment is complete, information about consent for data linkage will be sent in a supplementary PISC form 2A or 2B.

Factor 2: separate versus combined consent

Separate consent

Consent to data linkage for health and education data will be requested separately. PISC form 1B (concurrent) or 2B (delayed) will be used.

Combined consent

Consent to data linkage of health and education data will be requested as a single question. PISC form 1A (concurrent) or 2A (delayed) will be used.

All other details of the consent forms and information provided to participants will be otherwise identical (table 2).

Participants were randomised by simple computer-generated allocation sequence at the start of the ACORN trial, stratified by the clinical trial in which the child originally participated (pre-hPOD, hPOD or ProVIDe). The appropriate consent forms are computer generated and attached to the child's NIEOS record in a REDCap²⁸

database. Invitation letters and consent forms are generated from REDCap and viewed by participants online or printed hard copy.

The in-person assessment will be carried out if parents/caregivers consent to this, regardless of their decision about consent to data linkage. Parents/caregivers are also able to consent to data linkage even if they decline the in-person assessment. The ACORN trial will not determine any aspects of care for the participating child.

Blinding

This is a single-blind trial. Participants will be unaware of the intervention as they are unaware of the trial. It is not possible to blind members of the research team (study coordinators) as they will be discussing the study information with parents/caregivers as part of the informed consent process. Study coordinators will be aware of the participant's allocation but cannot change the allocation as the form was loaded onto the child's REDCap record at the time of randomisation. Analysis will be performed by researchers unaware of factor designation.

Outcomes

The primary outcome for factor 1 is the proportion of children for whom consent to any data linkage is obtained, and for factor 2 is the proportion of children for whom consent to linkage of both health and education data is obtained.

The secondary outcomes are consent to linkage of health data; consent to linkage of education data; consent to in-person assessment but not data linkage; consent to data linkage but not in-person assessment

Hypothesis

The primary hypothesis is that the rate of consent for data linkage will be increased if consent is sought after in-person assessment versus concurrently and if consent is sought for combined health and education data versus separately. The secondary hypothesis is that the rate of

Table 2 ACORN trial consent forms

Form number	Form name	Contents of form
1A	Participant information sheet and consent form 1A	Information about NIEOS Information about data linkage Consent form for the in-person assessment Consent form for data linkage (health and education combined)
1B	Participant information sheet and consent form 1B	Information about NIEOS Information about data linkage Consent form for the in-person assessment Consent form for data linkage (health and education separately)
2	Participant information sheet and consent form 2	Information about NIEOS Consent form for the in-person assessment
2A	Supplementary consent form 2A	Information about data linkage Consent form for data linkage (health and education combined)
2B	Supplementary consent form 2B	Information about data linkage Consent form for data linkage (health and education separately)

NIEOS, Neonatal Nutritional Intervention Early School-age Outcomes Studies .

consent (any or both) is related to ethnicity, socioeconomic status, birth gestation and primary neonatal trial cohort.

Statistical methods

Data are categorical and will be presented as number (n) and per cent (%). Participants will be analysed in the group to which they were randomised (intention-to-treat). In the primary analysis, primary and secondary outcomes will be compared between factor level groups using generalised linear models (binomial, logit link) accounting for clustering within study and pregnancy, and for the alternative factor. Exposure effects, determined from marginal means for each factor, will be presented as OR and 95% CI. Secondary analysis will explore factor interaction for rates of consent to any data linkage and for each factor and associated primary outcome the influence of primary neonatal trial (interaction test) and demographic variables (covariates of ethnicity, socioeconomic status, preterm birth). In the delayed consent group, parents who do not return a consent form within 3 months after two reminders will be considered to have declined consent for data linkage. There will be no other imputation of missing data. An overall $p < 0.05$ for either primary outcome will be considered significant, but apportioned for sequential testing according to the O'Brien-Fleming stopping Convention, such that the final critical p for between group comparisons will be $p < 0.0471$ assuming the threshold for early stopping had not been reached. Analysis will be performed with SAS V.9.4 (SAS Institute, 1989–2021).

Sample size

The sample size for the ACORN trial is limited by the number of babies recruited in each of the NIEOS trials. The primary trials recruited a total of 2998 babies, of whom 2638 were recruited in New Zealand. Assuming a contact rate of 90%, this is a potential eligible population of 2374 children. If the contact rate is 80%, the potentially eligible population would be 2110 children. Data from other New Zealand studies suggest consent to data linkage are likely to be obtained for a high proportion of children. When requested at 54 months, 97% of the *Growing Up in New Zealand* cohort parents/caregivers agreed to linkage of routine education data of their child up to 7 years.²⁹ In the PLUSS trial (Multicentre Randomised Controlled Trial of Surfactant Plus Budesonide to Improve Survival Free of Bronchopulmonary Dysplasia in Extremely Preterm Infants, ACTRN12617000322336), among 90 infants recruited in Auckland from May 2018 to May 2021 (recruitment ongoing), 86 (95%) had parental consent for health and education data linkage up to 16 years of age.

However, in both of these cohorts, consent was requested in a face-to-face interview, where there is greater opportunity to explain the reasons for, and processes of data linkage. Additionally, in the *Growing up in New Zealand* cohort, this consent only related to education data

linkage and for a shorter period of time. The PLUSS trial included significantly unwell children and requested data linkage very early, while the participants were neonates. Therefore, we expect the baseline rate of consent in the NIEOS population to be lower than in these studies. In a pilot study of the first 366 NIEOS participants, the overall consent rate for any data linkage was 93% (95% CI 90% to 95%).

The sample size was calculated using PASS software (NCSS, LLC, Kaysville, Utah, USA, V.16) using binomial enumeration since the proportions were anticipated to be > 0.8 . We estimated that with 1136 participants, the ACORN trial would have 90% power to detect an absolute difference of 5% in the primary outcome for each factor, assuming a consent rate of 90% (the lower limit of the CI) in the control groups and overall alpha of 0.05 for either primary outcome.

Interim analyses

Because there is no apparent possible risk to participants of this trial, there will be no independent Data Monitoring Committee. However, if one approach to seeking consent for data linkage is clearly superior to another, it will be important that the Steering Group is informed so that maximum data can be collected for NIEOS study participants. Interim analyses are therefore planned for consideration of early stopping approaches for superiority. Stopping the trial early for futility is not anticipated, given the sample size calculations. The study statistician will undertake interim analyses when recruitment reaches 400 and 800 participants in the delayed consent group (since the delay means the numbers recruited at any time is lower in this group than in the concurrent consent group) and present the results to the Steering Group as percentages rather than absolute numbers to maintain blinding to group allocation. O'Brien-Fleming stopping rules for superiority will be used, with the critical alpha of $p < 0.0006$ for the first examination, $p < 0.0151$ for the second and $p < 0.0471$ for the final investigation.³⁰

Trial management

The ACORN Steering Committee comprises the authors of this manuscript with the exception of Aakash Rajay. The Steering Committee will take overall responsibility for all aspects of the study, meeting on a regular basis. Matters arising between meetings may be dealt with by email. The Chair of the Steering Group will be responsible for maintaining a record of correspondence and minutes of meetings.

All amendments to the protocol will require review and approval of the Steering Committee and will be submitted to the Health and Disability Ethics Committee as appropriate. All amendments, including approval date, will be recorded.

A Study Coordinator will be appointed to oversee day-to-day running of the study. They will be supported by a Management Committee which will meet regularly.

Data management

Data will be collected in the REDCap data management system. If hard copy forms are returned, data will be entered at the data management centre into the REDCap electronic forms.

REDCap databases and raw electronic data files will be stored on secure servers at the University of Auckland and access will be controlled by unique user ID and password. Any hard copy records will be stored in a locked cabinet at the Liggins Institute. REDCap is HIPAA compliant and includes electronic case record form (eCRF) level control and tracking logs. eCRFs will be identifiable only by study number. Identifiable information will be stored in a separate REDCap database. Download of data will be restricted to the data management team and primary investigator. Downloaded data will be deidentified.

Study reports will contain only summary data and individual participant data will not be reported. At the completion of the study, all electronic data will be permanently digitally archived at the Liggins Institute. Any remaining hard copy records will be stored in a locked cabinet in a secure office and will be accessible only to the study investigators. Records will be retained for 10 years after the age of majority. All research staff will be certified in best practice for clinical trials (ICH-GCP E6 and PHRP).

The Steering Committee will oversee analysis, interpretation and reporting of results. Approval will be sought from the Steering Committee prior to publication of study data. Care will be taken to avoid duplication in reporting of results.

Patient and public involvement statement

Patients and/or the public were not involved in the design or conduct of this research. However, consumer reference groups will be involved in the interpretation, reporting and dissemination of results. Findings of the ACORN trial will also be sent to all participants at the conclusion of the trial.

ETHICS AND DISSEMINATION

Research ethics approval has been granted by the New Zealand Health and Disability Ethics Committee (19/STH/202). It is not possible to seek direct consent to take part in the ACORN trial because doing so may possibly alter the outcome of the trial. Regardless of randomisation factor, the information provided to all participants is identical. To minimise the risk of randomising children whose parents/caregivers may not want to be involved in this trial, only parents/caregivers of children who have previously agreed to be contacted for follow-up are potentially eligible for the ACORN trial. There is no foreseeable additional risk, burden, or benefit for participants in any allocation factor, and no effect on any aspect of care for the children, or communication with the parents/caregivers.

Participants can decline consent to data linkage or in-person assessment without affecting their decision

about the other study components. Participants who are allocated to be asked for consent to data linkage concurrently with consent to the in-person assessment may choose to consent to either, both or neither on the PISC. Participants who are allocated to being asked for consent to data linkage after the in-person assessment may choose to decline the in-person assessment on the PISC. In this case, they will then be asked whether they would like to consider participation in the data linkage component of the study verbally by a member of the study team and sent the relevant supplementary PISC if they agree.

The primary mode of research dissemination will be via peer-reviewed publication. In addition, presentation at scientific meetings, educational sessions and public fora will be conducted as appropriate.

DISCUSSION

Ensuring high rates of consent to data linkage is imperative in follow-up studies, as even small differences in rates of consent have the potential to significantly affect the conclusions, generalisability and translatability of the study findings. In a study of 2000 participants, a 5% increase in the rate of consent would be the equivalent of an extra 100 participants for whom linked data may be available. These additional participants would increase the potential power of the study, increasing the likelihood of detecting small differences between groups and maximising the potential value of the dataset to inform future research and clinical practice. We therefore based our initial sample size calculations on a 5% absolute increase in consent rates in the intervention groups.

We have based sample size estimates on the assumption that 80%–90% of potential participants will be able to be contacted and will therefore be eligible for participating in ACORN. Lower rates of contact may reduce the generalisability of the findings to the original trial cohorts, but not to other studies seeking consent for data linkage, because consent can only be sought once contact is made. Families of all children eligible for the NIEOS study have already given consent to be approached for further follow-up, and based on our previous experience with similar studies, we expect to be able to contact at least 80%.

The findings from the ACORN trial have the potential to inform and possibly change the way we and others request consent to data linkage in the future. It will give guidance on certain elements of form design and help ensure that we do not miss participants who may be willing to consent.

This will be the first New Zealand study looking at methods of seeking parental consent to data linkage, an area with immense potential that is becoming increasingly prominent in the health and medical research. This will also be one of very few studies internationally that investigates the factors influencing parent's consent to data linkage for their children, and to investigate an intervention intended to increase rates of consent for data linkage for school-age children. Due to the randomised trial design and large power of the study, the ACORN trial will

be able to determine the influence of these interventions and provide high-quality evidence about whether they impact on the rates of consent. The interventions being assessed are simple and do not require any additional resources compared with current practices of seeking consent, allowing the findings to rapidly inform future practices of seeking consent to data linkage.

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Contributors JEH is the lead author of the study protocol and principal investigator. The protocol was drafted by JEH and ABR with significant input from the NIEOS Steering Group (JMA, GB, CC, GG, NF, CMK, BM, JR and TW) who contributed to all revisions of the protocol. All authors approved the final protocol manuscript.

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