ISAAC

INTERNATIONAL STUDY OF ASTHMA AND ALLERGIES IN CHILDHOOD

Phase Three Manual

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Abbreviations:

IIDC	ISAAC International Data Centre
ISAAC	International Study of Asthma and Allergies in Childhood
WHO	World Health Organisation

1. What is ISAAC?

1.1 Purpose

ISAAC, the International Study of Asthma and Allergies in Childhood , was founded to maximise the value of epidemiological research into asthma, allergic rhinoconjunctivitis and atopic eczema through facilitating international collaboration. Although epidemiological research has the potential to add to our understanding of these conditions, previous studies have lacked standardisation in case-definition and methodology, thus limiting the value of spatial and temporal comparisons of the prevalence of these disorders. The ISAAC programme, comprising three phases, was designed to allow comparisons of the prevalence of these disorders between populations in different countries, thereby forming the basis for studies investigating the role of possible modifiable environmental factors that may ultimately lead to a reduction in the personal burden of these diseases. Phase One, completed in 156 centres from 56 countries, has exceeded expectations in providing for the first time a global 'picture' of the prevalence of asthma, allergic rhinoconjunctivitis and atopic eczema. This Phase Three Manual provides the information required for the completion of Phase Three field work. Contact addresses, for the Regional Coordinators, Phase Three Coordinator, the Steering Committee and the International Data Centre (IIDC) can be found on pages 91–94.

1.2 ISAAC Phase One aims

1. To describe the prevalence and severity of asthma, rhinitis and eczema in children living in different centres and to make comparisons within and between countries.

2. To obtain baseline measures for assessment of future trends in the prevalence and severity of these diseases.

3. To provide a framework for further aetiological research into genetic, lifestyle, environmental and medical care factors affecting these diseases.

1.3 ISAAC Phase Two aims

1. To describe the prevalence of 'objective' markers of asthma and allergies in children living in different centres, and to make comparisons within and between centres.

2. To assess the relation between the prevalence of 'objective' markers of asthma and allergies and the prevalence of symptoms of these conditions in children living in different centres.

3. To estimate to what extent the variation in the prevalence and severity of asthma and allergies in children between centres can be explained by differences in known or suspected risk factors or by differences in disease management.

4. To explore new aetiologic hypotheses regarding the development of asthma and allergies in children.

1.4 ISAAC Phase Three aims

1. To examine time trends in the prevalence of asthma, allergic rhinoconjunctivitis and atopic eczema in centres and countries which participated in Phase One.

2. To describe the prevalence and severity of asthma, allergic rhinoconjunctivitis and atopic eczema in centres and countries which are of interest but did not participate in Phase One.

3. To examine hypotheses at an individual level which have been suggested by the findings of Phase One, subsequent ecological analyses and recent advances in knowledge.

1.5 Overview of study design

Phase One: Assesses the prevalence and severity of asthma, allergic rhinoconjunctivitis and atopic eczema in defined populations. Phase One has been completed in over 156 centres from 56 countries[1,2,3,4].

Phase Two: Investigates possible aetiological factors, particularly those suggested by the findings of Phase One. Phase Two, coordinated by Dr Stephan Weiland, Munster, Germany, is in progress in over 25 centres. A Phase Two Manual has been printed and circulated to participating centres[5].

Phase Three: Is based on the same research design as Phase One and planned to commence in 2001. A complete data set must be received by the IIDC in Auckland, New Zealand, by November 2002.

1.5.1 Classification of Phase Three centres

Centres participating in Phase Three will be classified as follows:

- **Group A** are the centres that completed Phase One according to the ISAAC Phase One protocol and criteria of the ISAAC Steering Committee and IIDC. These centres include those that completed a late Phase One study to this standard. They will use the same methodology as was described in the Phase One Centre Report submitted by each centre to the IIDC at the completion of Phase One (refer IIDC for further copies if needed, contact number page 93).

- **Group B** will be centres from around the world that did not participate in Phase One (new Phase Three centres) or centres whose Phase One study did not conform to the ISAAC Phase One protocol and criteria of the ISAAC Steering Committee and IIDC.

This classification will enable the Steering Committee, Regional/National Coordinators and the IIDC to differentiate between these two groups and to give added assistance as and if required.

1.5.2 ISAAC Phase One and Three Manuals

The Phase One Manual[6], includes a detailed description of the history and scientific background of ISAAC. Group A already have the Phase One Manual. Group B (new centres) may request a copy of the Phase One Manual from the Regional Coordinator, however further information can also be

obtained from previous publications[1-4], including the rationale and methods paper[7] and the ISAAC website (http://isaac.auckland.ac.nz).

The Phase Three Manual is available in one of the following ways: a printed hard copy; a copy on disk; as an email attachment, from the website, http://isaac.auckland.ac.nz. Please contact your Regional Coordinator or the IIDC if you would like a printed copy to be sent to you (contact details page 91–92).

1.5.3 Expression of interest

A Phase Three 'expression of interest' form, has been in circulation since early 1999 and a database of Group A & B centres has begun. A copy of the 'expression of interest' form is included in this Manual and can be found on pages 58–59.

1.6 ISAAC Phase Three Core Protocol

The compulsory requirement is the study of children in the 13/14 year age group. A random sample of 3000 children aged 13/14 years (recruited from school class registers) will be invited to participate. They will complete the ISAAC core questionnaires on asthma, rhinitis and eczema (example pages 27–29).

A video questionnaire on asthma symptoms (example pages 30–32 & 83–84) is strongly recommended for this age group. The video, developed in response to translation problems with written questionnaires, was designed to overcome the problems inherent in the administration of written questionnaires in different languages. The video questionnaire has been validated[8,9,10,11] for the purpose of this study. For further information contact Julian Crane (details page 93).

Another strongly recommended component is for each centre to recruit an additional sample of 3000 children aged 6/7 years. Children, identified through school class registers, will take a questionnaire home and their parents asked to complete the core questionnaires on asthma, rhinitis, and eczema (example pages 34–36). The video questionnaire will **not** be administered to this age group.

The feasibility of including an extra questionnaire, designed to obtain information concerning some environmental factors, is being explored and if this questionnaire is developed, it will be available from the ISAAC website before the start of data collection (http://isaac.auckland.ac.nz).

Some centres may wish to incorporate the ISAAC core protocol into a larger or more focused investigation of asthma, rhinitis and eczema. The ISAAC core protocol has therefore been designed to accommodate additional questionnaire material and supplementary investigations, however, extra questions should be located after the core questions to remain consistent with the standardised methodology.

1.7 Requirements for Phase Three A and B centres

1. Each prospective centre must register with the IIDC and their Regional Coordinator. Registration forms are available from Regional Coordinators, the IIDC or found on page 60 of this Manual.

2. Each research centre is responsible for obtaining its own funding and ethical approval, however it is acknowledged that some centres may have difficulty arranging funding. Where there are funding difficulties the National or Regional Coordinators should be contacted, in the first instance, to discuss potential alternative sources of funding.

3. Each centre is responsible for coding, entering and forwarding a copy of the data, to the Regional Coordinator, or directly to the IIDC, Auckland, New Zealand by November 2002 (for details on coding and formats for sending data, see Data and Coding Transfer Section, pages 45–57).

4. When a Principal Investigator (or Collaborator) sends a completed Registration form to the IIDC (with a copy to the Regional Coordinator), a blank Centre Report, for the age group studied, will be sent from the IIDC to the centre. Questions on this report will enable a detailed research protocol to be kept by collaborators, showing how the ISAAC Phase Three protocol was implemented locally (please read the sample Centre Report pages 63–71).

5. Each centre may publish its own data without the approval of ISAAC, however, the IIDC should receive a copy of any independent publications to archive. All publications and communications arising from comparisons of more than five international centres require the approval and authorisation of the ISAAC Steering Committee.

From the Steering Committee

"We invite the widest possible participation in ISAAC Phase Three for both groups A & B. We envisage Phase Three to be as successful as Phase One. The commitment and dedication of every single person that participated in Phase One, contributed to its enormous success. We believe Phase Three to be a crucial part of the process by which the nature and causes of the global variation and increases in the prevalence of asthma, allergic rhinoconjunctivitis and atopic eczema may be understood. We wish you well for your research".

2. Development and administration of the project

2.1 History

(refer Phase One manual [6] for more detail)

The ISAAC programme emerged in March 1991, from pre-existing multinational collaborative projects from Auckland, New Zealand and Bochum, Germany, each investigating variations in childhood asthma at the population level.

In June 1991, a Steering Committee for the organisation of international collaborative studies of childhood asthma and allergies was formed by New Zealand (Auckland & Wellington), United Kingdom (London) and Germany (Bochum).

Since 1991, an ISAAC Steering Committee Meeting has been held annually.

2.2 Organisational structure

The organisation of ISAAC consists of:

- Collaborating Centres
- National Coordinators
- Regional Coordinators
- The Steering Committee (including the Executive)

The Steering Committee, a group of 23 scientists from around the world actively involved with ISAAC, meet yearly, to plan and discuss key issues. From this group, a selected 'Executive' has a regular bi-monthly telephone conference to discuss and resolve the more urgent issues. Contact numbers of the Steering Committee and Executive can be found on pages 91–94.

The Steering Committee appoint Regional Coordinators to be responsible for a broad region of the world. These regions are based on the six WHO regions of the world, since these are widely used and logically organised. In some instances a WHO region has been split into subregions.

The ISAAC regions and Regional Coordinators for Phase Three are:

WHO region	ISAAC region	Regional Coordinators appointed
Europe	Western Europe	Prof Ulrich Keil & Dr Stephan Weiland
	Eastern Europe/Baltics	Professor Bengt Björkstén
Americas	North America	Professor Greg Redding
	Latin America	Professor Javier Mallol
Africa	Africa/Anglophone	Professor Joseph Odhiambo
	Africa/Francophone	Professor Nadia Aït-Khaled
South East Asia	Indian subcontinent	Dr Jayant Shah
Western Pacific	Asia-Pacific	Dr Chris Lai
	Oceania	Professor Neil Pearce
Eastern Mediterranean	Eastern Mediterranean	Dr Stephen Montefort

The Regional Coordinators recruit National Coordinators, to be responsible for a single country (if there is more than one centre in a country). The National and Regional Coordinators meet, to recruit centres (Collaborating Centres), to identify the Principal Investigators and also to organise the implementation of Phase Three in their region. A National meeting should be held prior to the start of data collection. Contact numbers and addresses of the Regional Coordinators can be found on pages 91–92.

2.2.1 ISAAC Collaborating centres

The responsibilities of Collaborating Centres are to:

- complete and submit the Registration Document (page 60) to the IIDC and Regional Coordinator
- obtain funding
- obtain local ethical approval
- communicate with the National Coordinator
- attend Phase Three National implementation meetings
- carry out ISAAC Phase Three A or B according to the protocol in this manual
- send the completed data set to either the IIDC or the Regional Coordinator, by November 2002
- complete and submit a Centre Report (example pages 63–71) to the IIDC and Regional Coordinator on completion of Phase Three

Phase Three A centres will retain their existing country and centre numbers. Phase Three B centres will be issued with country and centre numbers by the IIDC (refer ‘Registration’ on page 16).

2.2.2 ISAAC National Coordinators

The responsibilities of National Coordinators are to:

- recruit and register Collaborating Centres and identify Principal Investigators

- circulate the Phase Three Manual and questionnaires
- organise translations of the questionnaires (if required) in accordance with the established protocol (pages 43–44). Precoding of the questionnaires for the language used is a requirement of Phase Three (see pages 43 and 72–75 for more details). Translated questionnaires are then circulated to participating centres
- organise a national meeting of Collaborating Centres to organise the implementation of Phase Three
- communicate regularly with the Collaborating Centres and provide assistance
- communicate regularly with the Regional Coordinator providing progress reports
- organise a national meeting of Collaborating Centres to discuss the Phase Three results

2.2.3 ISAAC Regional Coordinators

The responsibilities of Regional Coordinators are to:

- recruit National Coordinators
- acknowledge receipt of Registration Documents and notify National Coordinators accordingly
- organise a meeting of National Coordinators to organise the implementation of Phase Three (prior to the national meeting of Collaborating Centres and National Coordinators)
- assist National Coordinators with the translation of the questionnaires (and back translations) according to the established protocol (page 43), ensure precoding of language on questionnaires (pages 72–75) and approve the final version
- ensure that the National Coordinators have circulated the questionnaires and the Phase Three Manual to the Collaborating Centres
- send the translated questionnaires to the IIDC for archive
- assist with National meetings, ensure that National Coordinators provide regular progress reports and provide assistance to National Coordinators as required
- communicate with the Steering Committee, participate in the Steering Committee meetings and give the National Coordinators feedback from the meetings
- assist the National Coordinators to organise a meeting to discuss the Phase Three results

2.2.4 The ISAAC Steering Committee

The responsibilities of the Steering Committee are to:

- recruit Regional Coordinators
- assist with the Regional meetings

- communicate with Regional Coordinators and provide assistance when required
- coordinate the implementation and conduct of Phase Three
- coordinate the analyses and publications of data
- organise future international ISAAC meetings

2.2.5 The ISAAC Steering Committee Executive

The ISAAC programme, coordinated on a day-to-day basis by an executive, have a telephone conference bi-monthly. The current executive consists of:

- Innes Asher, Chair of the Steering Committee, IIDC Director
- Bengt Björkstén, Regional Coordinator
- Neil Pearce, Regional Coordinator, Publications Subcommittee
- David Strachan, Methods Development Subcommittee
- Stephan Weiland, Phase Two Coordinator

2.3 Funding

Each research centre is responsible for obtaining its own funding. Any difficulties regarding funding issues, should be discussed, in the first instance with the National or Regional Coordinators.

3. Scientific background

(refer Phase One Manual for scientific detail for Phase One[6,7])

ISAAC Phase One has described the prevalence of asthma, allergic rhinoconjunctivitis and atopic eczema in over 156 centres from 56 countries and has 'mapped' the prevalence of these conditions in two age groups (6/7 and 13/14 years of age)[1-4]. Brief summaries of results are as follows:

3.1 Asthma[1, 2]

For the 13/14 year age group, the range in self reported 12 month prevalence of symptoms of wheeze was very large, ranging from 2.1 – 4.4% in Albania, China, Greece, Georgia, Indonesia, Romania and Russia to 29.1 – 32.2% in Australia, New Zealand, Republic of Ireland and the UK. There were a number of interesting regional trends, including a strong Northwest (high) to Southeast (low) gradient within Europe. For the 6/7 year age group, parental reported 12 month prevalence of wheeze, ranged from 4.1 – 32.1% with lowest rates in India, Indonesia, Iran and Malaysia and highest rates in Australia, Brazil, Costa Rica, New Zealand and Panama. Some centres with extreme values in the older age group, did not provide data for the younger age group.

The international patterns of wheeze and asthma symptom prevalence that were observed could not be explained by our current understanding of the causation of asthma.

3.2 Rhinitis[1,3]

The prevalence of rhinitis with itchy-watery eyes ("allergic rhinoconjunctivitis") in the past year varied across centres from 0.8% – 14.9% in the 6/7 year olds and from 1.4% – 39.7% in the 13/14 year olds. Within each age group, the global pattern was broadly consistent across each of the symptom categories. In centres of higher prevalence there was great variability in the proportion of rhinoconjunctivitis labelled as hay fever. The lowest prevalence of rhinoconjunctivitis was found in parts of Eastern Europe, South and Central Asia. High prevalence was reported from centres in several regions. The results suggest substantial worldwide variations in the prevalence and labelling of symptoms of allergic rhinoconjunctivitis that require further study. These differences, if real, may offer important clues to environmental influences on allergy.

3.3 Eczema[1,4]

The prevalence range for symptoms of atopic eczema was similar in both age groups, from less than 2% to over 16% and less than 1% to over 17% in the 6/7 and 13/14 year age groups respectively. Higher prevalence of atopic eczema symptoms were reported in Australasia, Northern Europe and some centres in Africa and lower symptom prevalence was reported in Eastern and Central Europe and Asia. Similar patterns were seen for symptoms of severe atopic eczema. Symptoms of atopic eczema exhibit wide variations in prevalence both within and between countries inhabited by similar ethnic groups, suggesting that environmental factors may be critical in determining disease expression.

3.4 Significance of the proposed study

ISAAC Phase One, by using a simple standardised methodology has 'mapped' the prevalence of asthma, allergic rhinoconjunctivitis and atopic eczema in two age groups of school children in centres throughout the world and provided a framework for further study. Several ecological analyses of ISAAC Phase One worldwide data have been undertaken. The publications of these are found on the ISAAC website: http://isaac.auckland.ac.nz. ISAAC Phase Two, involving more intensive studies in a smaller number of centres (over 25), began in 1998. Phase Two, has been designed to investigate the relative importance of hypotheses of interest that have arisen from the Phase One results using objective markers. Standardised questions about cough, the medical care of asthma, rhinitis and eczema and child contact protocols have been developed[5].

ISAAC Phase Three has been designed to repeat as closely as possible the Phase One methodology used for each Phase One centre. As well, the recruitment of 'new' centres is encouraged, to obtain a more comprehensive global picture of asthma, allergic rhinoconjunctivitis and atopic eczema. The Phase Three studies are a crucial part of the process by which the extent, nature and causes of the global increases in the prevalence of these conditions may be understood. Phase Three is important, to determine the trends in the prevalence of asthma and allergic rhinoconjunctivitis and atopic eczema, to observe whether the trends are uniform throughout the world and to identify factors which may be related to these trends.

4. Phase Three Aims

1. To examine time trends in the prevalence of asthma, allergic rhinoconjunctivitis and atopic eczema in centres and countries which participated in Phase One.

2. To describe the prevalence and severity of asthma, allergic rhinoconjunctivitis and atopic eczema in centres and countries which are of interest but did not participate in Phase One.

3. To examine hypotheses at an individual level which have been suggested by the findings of Phase One, subsequent ecological analyses and recent advances in knowledge.

5. Phase Three Methods

5.1 Overview

Phase Three will begin from January 2001 (guidelines for fieldworkers are found on pages 41–44 and 72–75). A Centre Report and a complete data set (prepared as per the Coding and Data Transfer Section pages 45–57) must be received at the IIDC by 30 November 2002, for centres to be included in publications of worldwide data.

- **Group A** are the centres that completed Phase One according to the ISAAC Phase One protocol and criteria of the ISAAC Steering Committee and IIDC. This includes centres that submitted data too late for inclusion in the first worldwide publications, but was of the required standard.

- **Group B** are the centres from around the world that did not participate in Phase One but that now wish to participate in Phase Three (new centres), or Phase One centres that submitted data that did not conform to the ISAAC Phase One protocol and criteria of the ISAAC Steering Committee and IIDC.

The methodology described for this section of the manual, will at times, be divided into the two groups. This has the advantage of giving Group A centres the necessary information for them to proceed and will give more indepth information to the new Group B centres.

Group A:

Will conduct Phase Three in the same way as Phase One following, as precisely as possible, the details of the centre methodology documented in the Phase One Centre Report.

Each Principal Investigator was sent a final copy of the Phase One Centre Report from the IIDC (example page 63–71). However, further copies are available on request from the IIDC.

Group A will use:

- the same sampling frame, the exact same set of schools should **not** be aimed for, but some schools may be reselected by the random sampling process
- It is acknowledged that some centres will need to use all schools and therefore not select by

random sampling.

- the same age group/s
- the same sample size (see page 18 – sample size and power consideration)
- the same method of choosing the children
- the same written questionnaires (plus an environmental module)
- the same translation (if applicable)
- the same time of year for data collection
- the international version of the video (AVQ 3.0) for the 13/14 year olds

Group B:

Will proceed as per this Manual and document the methodology on the Centre Report (example pages 63–71) as the study progresses.

5.2 Registration

All Phase Three centres (Groups A & B) are required to register with the IIDC. The Registration Document (pages 60–62) is to be completed by each Principal Investigator and sent to the IIDC with a copy sent also to the Regional Coordinators. The Registration Document, a signed declaration that the Principal Investigator intends to carry out the study according to the ISAAC protocol, will identify further details of the study to be undertaken and provide the correct contact details of the Principal Investigator. This will enable the IIDC to update the database of collaborators and issue country and centre numbers to the 'new' Group B centres.

5.3 Collaborating centres

Group A:

Are the centres within countries that completed Phase One according to the ISAAC Phase One protocol and criteria of the ISAAC Steering Committee and IIDC. These centres will retain their existing centre and country code numbers, previously allocated by the IIDC. These can be found documented on the Phase One Centre Report or by contacting the IIDC (contact number page 93).

Group B:

Are centres from countries around the world that did not participate in Phase One but who now wish to undertake an ISAAC study, or Phase One centres that submitted data that did not conform to the ISAAC Phase One protocol and criteria of the ISAAC Steering Committee and IIDC. The ISAAC Steering Committee have defined an ISAAC research centre as: *a distinctive population in terms of its geography, race and/or ethnic characteristics, where one or more named investigators have agreed (by submitting a Registration Document) to follow the ISAAC study protocol described in this Manual.* New centres are particularly sought from regions where standardised prevalence data does not exist. Where existing data suggest regional differences in asthma or allergic diseases, participation of additional centres will also be encouraged. The sample of children taking part in ISAAC should not previously have been recruited systematically for research into asthma or

allergies (although individual children may have been so involved). However, investigators may wish to use ISAAC as the first stage in new local research about these conditions.

5.4 Investigators

Group A:

The ISAAC Phase One Principal Investigators and National Coordinators may no longer be involved with the study. The Registration Document and subsequent documentation will enable the IIDC to keep an accurate database of the Principal Investigators and National Coordinators for Phase Three. The Principal Investigators may differ from the person who actively communicates with the IIDC regarding the methodology and data and if this is the situation, we request that this is clearly communicated to the IIDC. This information is requested in the Registration Document (pages 60–62).

Group B:

There will be some investigators who have experience with asthma, rhinitis and eczema, or its epidemiology, especially in children, who wish to participate in the ISAAC programme as a new Phase Three centre. These centres will become the ISAAC Phase Three B centres. An 'expression of interest' form (pages 58–59) can be completed and returned to the IIDC to ensure these centres are included in the data base and that the IIDC has the correct contact name and address of the Principal Investigator. If the Principal Investigator is not the person who will be communicating with the IIDC concerning the day to day running of the study, then the IIDC needs to have this information.

5.5 Subjects

5.5.1 Selection

For both groups A and B, the 13/14 year age group is the compulsory component of ISAAC Phase Three. The video questionnaire for this age group is strongly recommended. The study of the 6/7 year age group is also strongly recommended.

Group A:

The selection of the children of each age group to be studied will follow the methods used for ISAAC Phase One and documented on the Phase One Centre Report. If centres studied both age groups, we recommend they study both age groups for Phase Three, however, we recognise that this may depend on the resources of the centre. We also encourage centres that did not study the 6/7 yr age group, to include them in Phase Three.

The centre methodology is detailed on the Phase One Centre Report which each centre should have a copy of. However, further copies are available on request from the IIDC (contact page 93).

- if grade/level/year was chosen for Phase One, then the children will be selected by the same grade/level/year for Phase Three
- if the children were selected by age group for Phase One, then they will again be selected by age

group - this applies also if the 'other' option was chosen

- similarly if Phase One used 'all children' or 'some children' then the same would be used for Phase Three
- please follow the exact methods as documented in your Phase One Centre Report
- If there are any difficulties, in the first instance, please contact your National Coordinator. If the National Coordinator cannot respond, contact your Regional Coordinator or IIDC (addresses pages 91–93).

Group B:

- We suggest you read the Centre Report form (pages 63–71) before you begin planning your study.
- the population of interest is school children within a given geographical area
- the compulsory requirement is to recruit a sample of at least 3000 13/14 year old children
- the 6/7 year age group is strongly recommended. We encourage centres to study this age group and if this age group is studied, a sample of at least 3000 children will be selected
- the sampling unit will be a school for each age group
- Each school in the centre that contains the age group of interest will be allocated a number. Some centres will need to use all schools in the sampling frame to obtain the required number of participants. For those that do not need to use all schools, schools should be chosen by random selection. Any other method must be documented.
- sampling of each age group, if both age groups are studied, will be separate
- once a school has been chosen, there are several ways of choosing the students:
  - grade/level/year where the classes with most children in the age group are selected
  - age group where only the children in the age group, regardless of grade/level/year are selected
  - and other methods, which may include elements of the above methods (you will find questions relating to this section in the Centre Report on pages 63–71)
- a minimum of 10 schools (or all the schools) per centre are needed to obtain a representative sample
- If a selected school refuses participation, then the school will be replaced by another chosen at random. No eligible children will be excluded from the sample unless documented.
- if a school for disabled children (e.g. blind, intellectually handicapped) is chosen, they will be studied
- It is acknowledged that there may be a disproportionate number of children of the 13/14 year age group who are unable to participate in such a school. This could be a reason for rejecting a school after it had been selected and if so, must be documented.

5.5.2 Sample size and power considerations

Group A centres:

Centres are required to achieve at least the same sample size as they did for Phase One. Those Phase One centres that were unable to reach the minimum number requested, should endeavour to

do so for Phase Three. However, there were a minority of centres who were unable to reach the minimum requirement despite using all the schools in the sampling frame. For Phase Three, the data from these centres will be treated as they were for Phase One, included in the analysis and appropriately identified in the publications.

Group B centres:

The sample size required to detect differences in severity of asthma is higher than that required to detect the same magnitude of differences in prevalence of asthma because severe asthma is less common. The sample size estimates are stringent because of the number of hypotheses being tested and the need to be certain of the results in such a major study. A sample size of 3000 for each age group was chosen for Phase One and this sample size will be used again for Phase Three. This gives the following power:

1. Prevalence of wheezing. If the true one year prevalence of wheezing is 30% in one centre and 25% in another centre, with a sample size of 3000, the study power to detect this difference will be 99% at the 1% level of significance.

2. Severity of wheezing. If the true one year prevalence of severe asthma is 5% in one centre and 3% in another centre with a sample size of 3000 the study power to detect this difference will be 90% at the 1% level of significance.

Table 1a

The yearly increase (decrease) in prevalence of symptoms of asthma and other allergic diseases detectable after 5 years with a power of 80% at the 5% level of significance for 3 initial levels of prevalence and four different sample sizes.

	5%	10%	20%
1000	0.6% (-0.5%)	0.8% (-0.7%)	1.1% (-1.0%)
2000	0.4% (-0.4%)	0.6% (-0.5%)	0.7% (-0.7%)
3000	0.3% (-0.3%)	0.5% (-.04%)	0.6% (-0.6%)
4000	0.3% (-0.3%)	0.4% (-0.4%)	0.5% (-0.5%)

Table 1b

The yearly increase (decrease) in prevalence of symptoms of asthma and other allergic diseases detectable after 5 years with a power of 90% at the 5% level of significance for 3 initial levels of prevalence and four different sample sizes.

	5%	10%	20%
1000	0.8% (-0.6%)	1.0% (-0.8%)	1.2% (-1.1%)
2000	0.5% (-0.4%)	0.7% (-0.6%)	0.9% (-0.8%)
3000	0.4% (-0.3%)	0.5% (-0.5%)	0.6% (-0.6%)
4000	0.3% (-0.3%)	0.5% (-0.4%)	0.6% (-0.6%)

It is recognised that some centres may have limited resources or populations but it is nevertheless desirable for them to be included in the prevalence comparisons. This summary table (Table 2) of sample size and power considerations shows the effect of changing sample size on the power of detecting differences in the prevalence of asthma:

Table 2 Sample Size and Power Considerations

Prevalence of asthma				
POWER (%) (significance level 1%)	Difference being tested			
Sample size	5% v 3%	5.5% v 3%	6% v 3%	6% v 4%
5000	99	>99	>99	98
4000	97	>99	>99	93
3000	90	98	99	82
2000	71	89	97	60
1000	34	53	71	26

5.6 Time period

The time period between the Phase One and Phase Three data collection will be at least 5 years. This has been chosen to be short enough to detect changes in centres where environmental changes may be occurring rapidly. Initially ISAAC Phase Three was timed for 3 years after Phase One, but a period of at least 5 years has now been chosen as it is more likely to detect the real magnitude of changes in prevalence that may have occurred. Therefore ISAAC Phase Three data collection will begin in January 2001, acknowledging that some centres will have a larger time period than 5 years between Phase One and Three. Some of the Phase One 6/7 year old children may be 'captured' as

13/14 year olds in Phase Three and may recall that their parents completed the questionnaire. However, this time, they will be self completing the questionnaire and it would be unlikely that they remember the content of the Phase One questionnaire if indeed they saw it at all.

5.7 Time trends

Phase Three will obtain the first internationally comparable estimates of the direction and magnitude of change in the prevalence of symptoms of asthma, allergic rhinoconjunctivitis and atopic eczema. Within countries, several time trend studies of the prevalence of asthma symptoms using a variety of methods have already been published and have been used for a crude estimation of the magnitude of the potential changes which may be found[12-22].

5.8 Study design

5.8.1 Details of the core modules

Three one page core questionnaires were developed at the International Study of Asthma and Allergies in Childhood workshop in Bochum, Germany, 8-10 December 1991. The aim of compiling "core" questionnaires was to ensure that comparable information on the basic epidemiology of asthma, rhinitis and eczema was obtained from as many populations as possible.

It is anticipated that individual investigators may wish to supplement the core questions with questions of their own, but they should ensure that the form of the questionnaire, including the flow and stemming, is unchanged. Any additional questions should come at the end of the core modules. Consideration must be given to the effect extra questions may have on participation rates. If centres use additional questions, the IIDC would like a copy of these to archive.

In Section 7 (pages 26–29), the core questionnaires are presented. For the 13/14 year olds the written questionnaires on wheezing, rhinitis and eczema are compulsory, and it is strongly recommended that they also complete the video questionnaire. The feasibility of including an environmental questionnaire is being explored and if this questionnaire is developed it will be available from the ISAAC website: http://isaac.auckland.ac.nz. Investigators are also strongly recommended to recruit the sample of 6/7 year olds, whose parents/guardians will be asked to complete the appropriate written questionnaires on wheezing, rhinitis and eczema. The following outline summarises this design:

Phase Three Modules	13/14 years	6/7 years
1. Core questionnaires on symptoms of asthma, rhinitis and eczema	compulsory	Strongly recommended
2. Environmental questionnaire	strongly recommended	Strongly recommended
3. Asthma video questionnaire	strongly recommended	not used

5.8.2 Video questionnaire

For Phase One, two versions of the video were distributed for use. The first version (the European version VQ2.1) was used in 33 centres. The international version (AVQ 3.0) was subsequently developed and used in the other centres. For Phase Three, all centres will use the international version of the video (AVQ 3.0). Copies of this video questionnaire will be distributed to all participating centres with copies of the Phase Three Manual. Additional copies of the video can be obtained from Julian Crane (address and contact details on page 93).

5.8.3 Season of data collection

Group A:

It is recommended that the data collection process will be undertaken at the same time of year as the Phase One data was collected. This information has already been given to the Phase One Collaborators who sent an 'expression of interest' form to the IIDC.

Group B:

The date of data collection must be documented and at least half of the study population should be investigated before the main pollen season of the study area.

5.9 Non-participation

Group A and Group B:

A participation rate of at least 90% is expected. It is a concern that absent children may be away from school because of asthma, rhinitis or eczema. Therefore strenuous efforts need to be made to contact these children and offer the opportunity of participation in the study. In the case of children where consent has been refused, demographic data (age, sex, ethnic group) will be sought, if possible, from the school. For the older age group, the reasons for non participation of students may be relatively easy to obtain and document. For example, some religious groups are not permitted to view a television, and in some circumstances, the students may complete the written core questionnaires and then depart from the room when the video is shown and therefore would not participate in this section.

In the case of the younger age group, if the initial questionnaire is not returned within one week, the information letter and questionnaire will be sent again via the school. An envelope (addressed and stamped) attached to the questionnaire may encourage participation. See the fieldworkers guide on pages 72–88.

5.10 Quality control

Particular importance is attached to the quality of the data collection and procedures in ISAAC, to ensure confidence in the results. An ISAAC Centre Report (example pages 63–71), will be sent to every collaborating centre to complete as the study progresses and return to the IIDC at the time of submitting the data to the IIDC. The deadline for receipt of the Centre Report is 30 November 2002.

This will provide a detailed account of the research methodology showing how the ISAAC Phase Three protocol was implemented locally. Key issues include: the geographical definition of the centre; the method for sampling schools and children; participation rates; data entry; the details regarding the method of translating the ISAAC core questionnaire into other language(s) and back translation to English, if appropriate and questions regarding the video (for the older age group). It is very important that centres contact the IIDC if they have any difficulties understanding the Centre Report (contact address page 93).

5.11 Presentation and Translation

It is important that the questionnaires are prepared in a consistent manner. The order of Yes/No responses has been defined. The layout and printing of the questionnaires will be standard with each module being printed on a single page. The questionnaires for the 13/14 year olds are usually presented on one piece of folded paper (A4 size when folded) with the video questionnaire to be showing on the back (when folded), or they may be presented separately, with adequate identification on each page. The IIDC can provide further advice on questionnaire layout if needed.

Translation of questionnaires from English to other languages will be standardised, by translating the English version and back translating to English by an independent person. See section 14 ‘Guidelines for the Translations of Questionnaires’ on page 43 and coding of language used on the questionnaires on page 75. It is important that these procedures are followed.

6. Data handling and analysis

Detailed instructions about coding and data transfer are found in Section 15 pages 45–57.

6.1 Data quality and handling

6.1.1 Demographic data

This data is the requested personal information for each individual participant. Ideally these questions should be well laid out, easy to complete and on the first page of the questionnaire (example pages 26 & 73). The questions ask for participants name, age, date of birth, school, male/female, the date of completing the questionnaire and optional questions on ethnicity. Office use boxes at the top of the first page allow the person conducting the survey to keep an account of the unique number for the participant and individual school as well as the number of times the questionnaire has been sent out. Further information is available in the field workers guide on page 72. It is advisable to precode the questionnaires for each age group before printing and to precode the language of the questionnaire to enable an exact account to be kept of numbers of translated questionnaires. A list of coding numbers for translations can be found on page 75. If your language is not listed, please contact Tadd Clayton at the IIDC (contact address page 93). Also refer page 72 for an example of coding ‘for office use only’ boxes.

Where comparisons between ethnic groups are planned, each individual centre should follow the question on ethnicity used in the most recent Census of Populations for that centre.

The completed questionnaire should be carefully checked if possible at the time of conducting the

survey (in the case of the older age group) or as soon as possible after collecting the questionnaires from the school. Any obvious errors with the demographic data, should be corrected by obtaining the information from the schools. Any changes made to the demographic data must be well documented, dated and signed by the person making the changes (see example page 88).

6.1.2 Core questionnaires

The data for asthma, rhinitis and eczema must be entered on to the computer exactly as it is presented in the questionnaire and **must not be changed under any circumstances**. If for some reason a questionnaire is altered, a copy of the data should be made before the changes and a record kept as to the reason why this change was made. It is vital that the original data is available to the IIDC. The questionnaire must **not** be altered for consistency between the stem and following questions. If some questions are left blank on a particular questionnaire, it will be at the discretion of the IIDC as to whether that questionnaire is excluded. The Coding and Data Transfer Section page 45 gives instructions on data handling, data entry and submission to the IIDC.

6.1.3 Data Entry

Each centre is responsible for coding its own data and data entry, although in some regions/countries, one centre may take responsibility for this. Data should be double entered. Double entry is a common method of data entry that minimises data entry errors and is the expected method of data entry for ISAAC. The data is entered two times, preferably by two different people. The two versions of the data set are compared and any differences checked against the original questionnaire. Dedicated data entry software (e.g. Epi Info) will allow the comparison between the first and second entry to occur as the second entry is made. Any inconsistencies can be resolved at that time based on the original questionnaire. If alternative methods are planned, these should be discussed in advance with the IIDC.

If centres wish to use an Epi Info data entry package, the ISAAC Epi Info package can be obtained from Tadd Clayton (address page 93) or the ISAAC website: http//isaac.auckland.ac.nz.

The questionnaires must be kept for a minimum of 3 years (or according to local rules) to allow checking against the computer record, if this should be necessary.

Data will be sent to the IIDC as detailed in the data and coding transfer section pages 45–57. Collaborators should expect an acknowledgement of receipt of data on its arrival at the IIDC. Please check this occurs, because mail can occasionally go astray. After acknowledgement of receipt of data, the data will undergo a number of checks at the IIDC and a report on the data will be issued to the Centre within 2 months. This report will provide a summary of the data checks made by the IIDC and will identify areas where a response is requested from the collaborating centre. This data checking process must be completed before centre data will be analysed in publications of worldwide Phase Three data. At the IIDC, centre data will be entered onto a PC with the necessary statistical analysis capabilities and a copy of the data will be kept off site in a protected environment. Collaborators are encouraged to visit the IIDC.

6.1.4 Satisfactory Data Set

Centres that wish to be included in ISAAC Phase Three worldwide publications must provide a complete data set and Centre Report to the IIDC by 30 November 2002. The data and the Centre Report will then undergo a checking process by the IIDC in conjunction with each centre. A

satisfactory data set is one which is prepared according to the Coding and Data Transfer Section and which has completed the data checking processes above.

6.2 Analysis

Each group of participants will be treated separately: 6/7 year olds, 13/14 year olds. Each parameter of prevalence and severity will be compared between locations. The cluster effect is not expected to be great, but will be adjusted for in the analysis.

Group A:

The primary aim of Phase Three is to obtain internationally comparable estimates of the direction and magnitude of change in prevalence of symptoms of asthma, allergic rhinoconjunctivitis and atopic eczema.

For Group A, Phase Three will:

- provide estimates of the direction and magnitude of the prevalence of symptoms of asthma and other allergies
- allow ecological studies of these trends
- allow confirmation (or otherwise) of previously hypothesised associations

Group B:

The objective of the study is to describe the prevalence and severity of asthma, allergic rhinoconjunctivitis and atopic eczema in centres and countries which are of interest but did not participate in Phase One.

Comparisons of prevalence rates between different centres will be made using appropriate statistical methods. Crude rates can be compared by using contingency tables or logistic regression. Comparison of standardised rates or data that needs controlling for confounding will involve multivariate logistic regression.

6.3 Ownership of data

Each centre owns their own data. The collaborating centres will be recognised by the group title “International Study of Asthma and Allergies in Childhood Phase Three Study Group”. All publications and communications involving international comparisons will have a named writing group “and the ISAAC Phase Three Study Group”. All Principal Investigators will be acknowledged in the appendix of publications of worldwide data.

Each centre may publish its own data without the approval of ISAAC, however, the IIDC should receive a copy of any independent publications to archive. All publications and communications arising from comparisons of more than five international centres require the approval and authorisation of the ISAAC Steering Committee.

7. Study instruments for 13/14 year olds

7.1 Instructions for completing questionnaire and demographic questions

Examples of instructions for completing questionnaires and demographic questions are given below. **The questionnaire content is fixed.** *(see pages 72–73 for 'office use only' boxes example)*

On this sheet are questions about your name, school, and birth dates. Please write your answers to these questions in the space provided.

All other questions require you to tick your answer in a box. If you make a mistake put a cross in the box and tick the correct answer. Tick only one option unless otherwise instructed.

Examples of how to mark questionnaires: Age [13] years

To answer Yes/No, put a tick in the appropriate box as per example

	YES	NO
	[ ]	[✓]

SCHOOL: [ ]

TODAY'S DATE: [ ] Day [ ] Month [ ] Year

YOUR NAME: [ ]

YOUR AGE: [ ] years

YOUR DATE OF BIRTH: [ ] Day [ ] Month [ ] Year

(Tick all your answers for the rest of the questionnaire)

Are you: MALE [ ] FEMALE [ ]

Optional questions on ethnicity here

7.2 Core questionnaire for asthma

7.2.1 Questionnaire for 13/14 year olds

1 Have you ever had wheezing or whistling in the chest at any time in the past?

Yes ☐
No ☐

IF YOU HAVE ANSWERED "NO" PLEASE SKIP TO QUESTION 6

---

2 Have you had wheezing or whistling in the chest in the past 12 months?

Yes ☐
No ☐

IF YOU HAVE ANSWERED "NO" PLEASE SKIP TO QUESTION 6

---

3 How many attacks of wheezing have you had in the past 12 months?

None ☐
1 to 3 ☐
4 to 12 ☐
More than 12 ☐

4 In the past 12 months, how often, on average, has your sleep been disturbed due to wheezing?

Never woken with wheezing ☐
Less than one night per week ☐
One or more nights per week ☐

5 In the past 12 months, has wheezing ever been severe enough to limit your speech to only one or two words at a time between breaths?

Yes ☐
No ☐

---

6 Have you ever had asthma?

Yes ☐
No ☐

7 In the past 12 months, has your chest sounded wheezy during or after exercise?

Yes ☐
No ☐

8 In the past 12 months, have you had a dry cough at night, apart from a cough associated with a cold or chest infection?

Yes ☐
No ☐

7.3 Core questionnaire for rhinitis

7.3.1 Questionnaire for 13/14 year olds

All questions are about problems which occur when you DO NOT have a cold or the flu.

1 Have you ever had a problem with sneezing, or a runny, or blocked nose when you DID NOT have a cold or the flu?

☐ Yes
☐ No

IF YOU HAVE ANSWERED "NO" PLEASE SKIP TO QUESTION 6

---

2 In the past 12 months, have you had a problem with sneezing, or a runny, or blocked nose when you DID NOT have a cold or the flu?

☐ Yes
☐ No

IF YOU HAVE ANSWERED "NO" PLEASE SKIP TO QUESTION 6

---

3 In the past 12 months, has this nose problem been accompanied by itchy-watery eyes?

☐ Yes
☐ No

4 In which of the past 12 months did this nose problem occur? (Please tick any which apply)

January	☐	May	☐	September	☐
February	☐	June	☐	October	☐
March	☐	July	☐	November	☐
April	☐	August	☐	December	☐

5 In the past 12 months, how much did this nose problem interfere with your daily activities?:

☐ Not at all
☐ A little
☐ A moderate amount
☐ A lot

---

6 Have you ever had hayfever?

☐ Yes
☐ No

7.4 Core questionnaire for eczema

7.4.1 Questionnaire for 13/14 year olds

1 Have you ever had an itchy rash which was coming and going for at least six months?

Yes ☐
No ☐

IF YOU HAVE ANSWERED "NO" PLEASE SKIP TO QUESTION 6

---

2 Have you had this itchy rash at any time in the past 12 months?

Yes ☐
No ☐

IF YOU HAVE ANSWERED "NO" PLEASE SKIP TO QUESTION 6

---

3 Has this itchy rash at any time affected any of the following places:

the folds of the elbows, behind the knees, in front of the ankles, under the buttocks, or around the neck, ears or eyes?

Yes ☐
No ☐

4 Has this rash cleared completely at any time during the past 12 months?

Yes ☐
No ☐

5 In the past 12 months, how often, on average, have you been kept awake at night by this itchy rash?

Never in the past 12 months ☐
Less than one night per week ☐
One or more nights per week ☐

---

6 Have you ever had eczema?

Yes ☐
No ☐

7.5 ISAAC International Video Questionnaire answer sheet

If the video questionnaire is included with the core questionnaires, the demographic details will have been put onto the front of the questionnaire. If the video questionnaire is administered separately, the demographic questions will need to be added to this section.

SCENE ONE:	The first scene is of a young person at rest.		
QUESTION ONE:	Has your breathing been like this, at any time in your life?	**YES**	**NO**
if **YES:**	has this happened in the past year?	**YES**	**NO**
if **YES:**	has this happened one or more times a month?	**YES**	**NO**
SCENE TWO:	The second scene is of two young people exercising. One is in a dark shirt and the other is in a white shirt.		
QUESTION TWO:	Has your breathing been like the boy's in the dark shirt during or following exercise at any time in your life?	**YES**	**NO**
if **YES:**	has this happened in the past year?	**YES**	**NO**
if **YES:**	has this happened one or more times a month?	**YES**	**NO**
SCENE THREE:	The third scene is of a young person waking at night.		
QUESTION THREE:	Have you been woken at night like this at any time in your life?	**YES**	**NO**
if **YES:**	has this happened in the past year?	**YES**	**NO**
if **YES:**	has this happened one or more times a month?	**YES**	**NO**
SCENE FOUR:	The fourth scene is also of a young person waking at night.		
QUESTION FOUR:	Have you been woken at night like this at any time in your life?	**YES**	**NO**
if **YES:**	has this happened in the past year?	**YES**	**NO**
if **YES:**	has this happened one or more times a month?	**YES**	**NO**
SCENE FIVE:	The final scene is of another person at rest.		
QUESTION FIVE:	Has your breathing been like this at any time in your life?	**YES**	**NO**
if **YES:**	has this happened in the past year?	**YES**	**NO**
if **YES:**	has this happened one or more times a month?	**YES**	**NO**

7.6. Video questionnaire verbal instructions

(see page 83 for detailed guidelines)

Instructions to be read out once the video is running:

*THIS IS A VIDEO QUESTIONNAIRE WHICH IS BEING SEEN BY YOUNG PEOPLE ALL OVER THE WORLD.

IT IS DESIGNED TO ASK YOU QUESTIONS ABOUT YOUR BREATHING.

YOU WILL BE SHOWN SOME SCENES OF YOUNG PEOPLE IN DIFFERENT SITUATIONS, FROM DIFFERENT COUNTRIES.

AFTER EACH SCENE, SOME NUMBERED QUESTIONS WILL BE READ OUT TO YOU.

TICK YES OR NO.

PLEASE ANSWER THE QUESTIONS AS YOU GO.

*THE FIRST SCENE IS OF A YOUNG PERSON AT REST.

(First scene comes on here)

*QUESTION 1. HAS YOUR BREATHING BEEN LIKE THIS AT ANY TIME IN YOUR LIFE?

IF YES, HAS THIS HAPPENED IN THE PAST YEAR?

IF YES, HAS THIS HAPPENED ONE OR MORE TIMES A MONTH?

*THE SECOND SCENE IS OF TWO YOUNG PEOPLE AFTER EXERCISE. ONE IS IN A DARK SHIRT, AND ONE IS IN A LIGHT SHIRT.

(Second scene comes on here)

*QUESTION 2. HAS YOUR BREATHING BEEN LIKE THE BOY'S IN THE DARK SHIRT FOLLOWING EXERCISE AT ANY TIME IN YOUR LIFE?

IF YES, HAS THIS HAPPENED IN THE PAST YEAR?

IF YES, HAS THIS HAPPENED ONE OR MORE TIMES A MONTH?

*THE THIRD SCENE IS OF A YOUNG PERSON WAKING AT NIGHT.

(Third scene comes on here)

*QUESTION 3. HAVE YOU BEEN WOKEN AT NIGHT LIKE THIS AT ANY TIME IN YOUR

LIFE?

IF YES, HAS THIS HAPPENED IN THE PAST YEAR?

IF YES, HAS THIS HAPPENED ONE OR MORE TIMES A MONTH?

*THE FOURTH SCENE IS ALSO OF A YOUNG PERSON WAKING AT NIGHT.

(Fourth scene comes on here)

*QUESTION 4. HAVE YOU BEEN WOKEN AT NIGHT LIKE THIS AT ANY TIME IN YOUR LIFE?

IF YES, HAS THIS HAPPENED IN THE PAST YEAR?

IF YES, HAS THIS HAPPENED ONE OR MORE TIMES A MONTH?

*THE FINAL SCENE IS OF ANOTHER PERSON AT REST.

(Fifth scene comes on here)

*QUESTION 5. HAS YOUR BREATHING BEEN LIKE THIS AT ANY TIME IN YOUR LIFE?

IF YES, HAS THIS HAPPENED IN THE PAST YEAR?

IF YES, HAS THIS HAPPENED ONE OR MORE TIMES A MONTH?

*THANK YOU FOR TAKING PART IN THIS PROJECT.

8. Study instruments for 6/7 year olds

8.1 Instructions for completing questionnaire and demographic questions

Examples of instructions for completing questionnaire and demographic questions are given below.

The content of the questionnaires is fixed. *(see pages 72–73 for 'office use only' boxes example)*

On this sheet are questions about your child's name, school, and birth dates. Please write your answers to these questions in the space provided.

All other questions require you to tick your answer in a box. If you make a mistake put a cross in the box and tick the correct answer. Tick only one option unless otherwise instructed.

Examples of how to mark questionnaires: Age [6] years

To answer Yes/No, put a tick in the appropriate box as per example

	YES	NO
	☐	✓

SCHOOL: ☐

TODAY'S DATE: ☐ Day ☐ Month ☐ Year

CHILD'S NAME: ☐

CHILD'S AGE: ☐ years

CHILD'S DATE OF BIRTH: ☐ Day ☐ Month ☐ Year

(Tick all your answers for the rest of the questionnaire)

Is your child a: MALE ☐ FEMALE ☐

Optional questions on ethnicity here

8.2 Core questionnaire for asthma

8.2.1 Questionnaire for 6/7 year olds (strongly recommended)

1 Has your child ever had wheezing or whistling in the chest at any time in the past?
- Yes ☐
- No ☐

IF YOU HAVE ANSWERED "NO" PLEASE SKIP TO QUESTION 6

---

2 Has your child had wheezing or whistling in the chest in the past 12 months?
- Yes ☐
- No ☐

IF YOU HAVE ANSWERED "NO" PLEASE SKIP TO QUESTION 6

---

3 How many attacks of wheezing has your child had in the past 12 months?
- None ☐
- 1 to 3 ☐
- 4 to 12 ☐
- More than 12 ☐

4 In the past 12 months, how often, on average, has your child's sleep been disturbed due to wheezing?
- Never woken with wheezing ☐
- Less than one night per week ☐
- One or more nights per week ☐

5 In the past 12 months, has wheezing ever been severe enough to limit your child's speech to only one or two words at a time between breaths?
- Yes ☐
- No ☐

---

6 Has your child ever had asthma?
- Yes ☐
- No ☐

7 In the past 12 months, has your child's chest sounded wheezy during or after exercise?
- Yes ☐
- No ☐

8 In the past 12 months, has your child had a dry cough at night, apart from a cough associated with a cold or chest infection?
- Yes ☐
- No ☐

8.3 Core questionnaire for rhinitis

8.3.1 Questionnaire for 6/7 year olds (strongly recommended)

1 Has your child ever had a problem with sneezing, or a runny, or blocked nose when he/she DID NOT have a cold or the flu?

Yes ☐
No ☐

IF YOU HAVE ANSWERED "NO" PLEASE SKIP TO QUESTION 6

---

2 In the past 12 months, has your child had a problem with sneezing, or a runny, or blocked nose when he/she DID NOT have a cold or the flu?

Yes ☐
No ☐

IF YOU HAVE ANSWERED "NO" PLEASE SKIP TO QUESTION 6

---

3 In the past 12 months, has this nose problem been accompanied by itchy-watery eyes?

Yes ☐
No ☐

4 In which of the past 12 months did this nose problem occur? (Please tick any which apply)

January	☐	May	☐	September	☐
February	☐	June	☐	October	☐
March	☐	July	☐	November	☐
April	☐	August	☐	December	☐

5 In the past 12 months, how much did this nose problem interfere with your child's daily activities?:

Not at all ☐
A little ☐
A moderate amount ☐
A lot ☐

---

6 Has your child ever had hayfever?

Yes ☐
No ☐

8.4 Core questionnaire for eczema

8.4.1 Questionnaire for 6/7 year olds (strongly recommended)

1 Have your child ever had an itchy rash which was coming and going for at least six months?
- Yes ☐
- No ☐

IF YOU HAVE ANSWERED "NO" PLEASE SKIP TO QUESTION 7

---

2 Has your child had this itchy rash at any time in the past 12 months?
- Yes ☐
- No ☐

IF YOU HAVE ANSWERED "NO" PLEASE SKIP TO QUESTION 7

---

3 Has this itchy rash at any time affected any of the following places:
- Yes ☐
- No ☐

the folds of the elbows, behind the knees, in front of the ankles, under the buttocks, or around the neck, ears or eyes?

4 At what age did this itchy rash first occur?
- Under 2 years ☐
- Age 2-4 years ☐
- Age 5 or more ☐

5 Has this rash cleared completely at any time during the past 12 months?
- Yes ☐
- No ☐

6 In the past 12 months, how often, on average, has your child been kept awake at night by this itchy rash?
- Never in the past 12 months ☐
- Less than one night per week ☐
- One or more nights per week ☐

---

7 Has your child ever had eczema?
- Yes ☐
- No ☐

9. Validation of instruments

For a detailed discussion on development of the questionnaires and their validation, please refer to the ISAAC Phase One manual, section 7.0 (pages 22-29), publications arising from Phase One analyses[1-4] and the rationale and methods paper[7]. The questions used for Phase One were both sensitive and specific for the conditions.

10. Ethics Committee approval

Each participating centre will need to obtain the necessary Ethics Committee approval from their local Ethics Committee prior to the start of the study and document this on the Centre Report.

11. Model for approaching schools

What follows is one example of the approach to schools. Centres must proceed according to their local rules. A final goal should be a high participation rate.

Once the local Ethics Committee approval has been obtained, the school principal will be approached for his/her cooperation with the study. It may be helpful to offer to meet the staff to explain the study to them. An informal meeting at the morning break can be a good way to gain the cooperation of the teaching staff. The data collection can then commence. It is very important that asthma, allergies, rhinitis and eczema are not explicitly mentioned to school staff, pupils and parents in relationship to the study.

11.1 Sample information letter for schools (13/14 year old age group)

Dear Chairman of Board of Trustees/Principal/Teachers

re: New Zealand Survey of Breathing, Nose and Skin Problems in Children: Phase Three

We are inviting some children at your school to take part in an important international study with the approval of their parents. Many schools in Auckland took part in Phase One of the study in 1992, and by random sampling techniques, your school has been selected to participate in Phase Three. We wish to study children aged 13 and 14 years to understand more about the increasing problem of respiratory and skin symptoms in children of this age group.

This survey is being carried out in randomly selected schools in Auckland, Wellington, Christchurch, Nelson, Bay of Plenty, Hawke's Bay, and many overseas countries (more that 70 countries are expected to participate). The Auckland survey is being funded by the Health Research Council of New Zealand.

For your school, it would mean:

1. Identifying classes in which 13/14 year olds are found and making available a copy of the class lists with date of birth and gender if possible.

2. During this term one of our research team would bring information sheets for parents (copy enclosed) to the school, to be distributed to all the selected children one week before the study team come to your school.

3. We would return the next week to ask these children to complete written questionnaires (copy enclosed) and to watch a video about exercise and breathing which lasts about ten minutes. We would require about 40 minutes in total.

4. We would come back about a week later, with the questionnaires and show the video to any children who were absent on the first occasion an ask them to complete the survey.

One of our research team will be in contact with you soon to discuss this survey further. In the meantime if there is any further information you require about the survey, please do not hesitate to contact us by ringing 3737599 ext 6451.

This survey has the approval of the University of Auckland Human Subjects Ethics Committee, whose Chairman you may contact directly about ethical matters (care of the Secretary, University of Auckland Human Subjects Ethics Committee, University of Auckland, Private Bag 92019, Auckland; phone 373-7599, ext 6204).

Yours sincerely

NAME(S) and ADDRESS(ES)

11.2 Sample information letter for schools (6/7 year old age group)

Dear Chairman of Board of Trustees/Principal/Teachers

re: New Zealand Survey of Breathing, Nose and Skin Problems in Children: Phase Three

We are inviting some children at your school to take part in an important international study with the approval of their parents. Many schools in Auckland took part in Phase One of the study in 1992, and by random sampling techniques, your school has been selected to participate in Phase Three. We wish to study children aged 6 to 7 years to understand more about the increasing problem of respiratory and skin symptoms in children of this age group.

This survey is being carried out in randomly selected schools in Auckland, Wellington, Christchurch, Nelson, Bay of Plenty, Hawke's Bay, and many overseas countries (more than 70 countries are expected to participate). The Auckland survey is being funded by the Health Research Council of New Zealand.

For your school, it would mean:

5. Identifying classes in which 6/7 year olds are found and having ready a copy of the class lists for the researcher.

6. One of our research team will then come and name each survey form and distribute them by class to be taken home.

7. We will send information sheets, and questionnaires (copies enclosed) to the parents of the children who will be asked to complete the questionnaire and return it to your school, to be collected by the researcher.

8. We would follow-up any non-returned forms.

9. We would wish to have information on the date of birth and sex of any potentially eligible children who do not participate in the survey.

One of our research team will be in contact with you soon to discuss this survey further. In the meantime if there is any further information you require about the survey, please do not hesitate to contact us on 3737 599 ext 6451.

This survey has the approval of the University of Auckland Human Subjects Ethics Committee, whose Chairman you may contact directly about ethical matters (care of the Secretary, University of Auckland Human Subjects Ethics Committee, University of Auckland, Private Bag 92019, Auckland; phone 373-7599, ext 6204).

Yours sincerely

NAME(S) and ADDRESS(ES)

12. Model for approaching parents

An information sheet will be sent home with each participating child, giving details about the study. The information sheet will be translated into the most common languages used by families of eligible children.

13/14 year olds: The information sheet may include an additional paragraph giving the parent the right to refuse their child's participation in the study.

6/7 year olds: Parents completion and return of the questionnaire implies consent, however, centres should follow requirements of their local Ethics Committee.

12.1 Sample information sheet for parents/guardians of 13/14 year olds

Dear Parent/Guardian

We are inviting your child to take part in an important survey about child health with the approval of your school. Many schools in Auckland are taking part in the study and all the children in your child's class are being asked to take part. First, your child will be asked to complete three brief questionnaires, then a 10 minute video about exercise and breathing will be shown to your child in his/her class and your child will be asked to complete a further brief questionnaire. This will take up to 40 minutes of class time.

This survey is being carried out in randomly selected schools in Auckland, Wellington, Christchurch, Nelson, Bay of Plenty, Hawke's Bay and many overseas countries (more than 70 countries are expected to participate). The Auckland survey is funded by the Health Research Council of New Zealand.

We ask you to consider this information sheet, and if you agree to your child taking part in the survey, then you need to take no action. Your child's questionnaire will be treated confidentially; only a code number will be entered in the computer. If you do not wish your child to answer the questionnaire, please telephone the number listed at the bottom of this page tomorrow.

This survey has the approval of your child's school's Board of Trustees, Principal and Teachers. It also has the approval of the University of Auckland Human Subjects Ethics Committee whose Chairman you may contact directly about ethical matters (care of Mr G J Sanderson, Secretary, University of Auckland Human Subjects Ethics Committee, University of Auckland, Private Bag 92019, Auckland; phone 373-7599, ext 6204).

If there is any further information you require about the study, please contact one of us.

Yours sincerely

NAME(S)

CONTACT NUMBERS AND ADDRESS

12.2 Sample information sheet for parents/guardians of 6/7 year olds

Dear Parent/Guardian

We are inviting your child to take part in an important survey about child health with the approval of your school. Many schools in Auckland are taking part in the study and all classmates of your child are being asked to take part. For each child, a parent/guardian is being asked to complete a questionnaire.

This survey is being carried out in randomly selected schools in Auckland, Wellington, Christchurch, Nelson, Bay of Plenty, Hawke's Bay and also in many overseas countries (more than 70 countries are expected to participate). The Auckland survey is funded by the Health Research Council of New Zealand.

We ask you to consider this information sheet, and if you agree to your child taking part in the survey, then we would like you to complete the attached questionnaire. Your child's questionnaire will be treated confidentially; only a code number will be entered in the computer.

This survey has the approval of your child's school's Board of Trustees, Principal and Teachers. It also has the approval of the University of Auckland Human Subjects Ethics Committee.

If there is any further information you require about the study, please contact one of us.

Yours sincerely

NAME(S)

CONTACT NUMBERS AND ADDRESS

13. Field work

(More detailed guidelines for fieldworkers are included for those centres who wish to have extra detail and can be found on Page 72)

ISAAC research staff and field workers should not use the terms: asthma, allergy, rhinitis or eczema when:

- advertising the study
- presenting written material about the study
- speaking about the study to school staff, parents, children
- speaking to 13/14 year old children in the classroom.

The phrases "breathing nose and skin survey" or "a survey about breathing, nose and skin problems" are acceptable terms to use.

The title of the questionnaires must not include the words asthma, allergy, rhinitis, eczema or ISAAC. An alternative title could be "… survey of Breathing, Nose and Skin Problems" (example

page 73). Coding instructions for data entry, should not appear on the questionnaires delivered to the children or their parents, although coding boxes 'for office use only' are recommended (see example page 72–73).

13/14 year olds

The questionnaires will be administered to groups of children, in a school, one session at a time. Each session will comprise verbal instructions on the three sections before handing the questionnaires out, and instructions to leave the video questions until the video is shown. Alternatively, the questionnaires may be presented on separate sheets of paper. Administration will then include:

- handing out and completion of the written questionnaire on asthma
- handing out and completion of the written questionnaire on rhinitis
- handing out and completion of the written questionnaire on eczema
- The order of presentation of the core questionnaires is of importance: they should always be presented asthma-rhinitis-eczema.
- handing out the written questions for the video questionnaire followed immediately by the showing of the video questionnaire
- The written questions concerning the scenes in the video are completed while this is being hown. The video questionnaire must always be shown after the written questionnaires

In presenting the video, there must be adequate equipment with sufficient visual and audio quality to ensure all participants see it well and hear it correctly.

If questionnaires have clearly not been completed in a comprehensible fashion, then they could be re-presented to the person who originally completed them for one further attempt. The research worker should not give advice about the responses that might be given (see pages 78–83 for guidelines for fielding questions). Once the questionnaire is completed, **it must not be changed by research workers under any circumstances** (except that incorrect demographic details may be corrected with the help of pupil, school staff or school records).

6/7 year olds

Once eligible children are identified, ISAAC staff will send the questionnaire to the parent/guardian either through the school or by post. The parent/guardian will be asked to return the questionnaire by a mechanism which incurs no financial cost to them.

14. Guidelines for the Translation of Questionnaires

There already exists, an archive of translated questionnaires at the IIDC. On page 75 there is a list of languages used by centres for Phase One.

- **Group A** - should use the same translated version as they used for Phase One. If additional copies are required, they may be obtained from either the Regional Coordinator or from the IIDC.

- **Group B** - a translated questionnaire for your centre is likely to be available from your Regional Coordinator or from the IIDC (contact details page 91–93).

For those centres and countries where there are no existing translated questionnaires, the following guidelines have been compiled.

The following Steps are recommended for the translation of questionnaires

10. The questionnaires are translated by one or more persons who are bilingual and familiar with the area in which the questionnaire will be used.

11. In order to find the most appropriate translation for difficult terms, e.g.: “wheezing” or “whistling in the chest”, it is proposed to:

    (a) Ask local doctors about local words to describe these terms.

    (b) Ask children with asthma and parents of children with asthma how they would describe the breathing during an asthma episode.

    (c) Show the video and ask children with asthma and parents of children with asthma how they would describe the breathing of the children and adolescents in the video.

    (d) Submit a list of possible descriptors to children with asthma and parents of children with asthma and ask them to indicate, e.g. using a rating system, which description(s) they favour best.

12. The most appropriate translation should be agreed upon among a group of national experts on the basis of 2(a) – 2 (d). The national questionnaires should allow for differences in the wording of questions according to the local use of language.

13. The questionnaires are required to be translated back into English by an independent translator. Modifications should be made if necessary.

14. The questionnaires should be tested in populations representative of the study populations. Modifications should be made if necessary.

15. Steps 2 to 5 are repeated if necessary.

Comment

The translation of questionnaires is a key issue for the validity of comparisons involving non-

English speaking countries. It is recognised however, that the Steps 2(c) and 2(d) may be too costly for some countries or centres and that those countries or centres may decide to leave them out. The translated questionnaires must have the same structure and logic as the original. In addition, we draw the attention to the need that the translations must be understood by the children and parents. Thus, the translations should apply the language which is used by the children and parents themselves and experience from Germany shows that it may well differ from the terminology of medical professionals[23].

NOTE

The language used, should be precoded onto the questionnaire prior to printing the questionnaires. All the languages that were used for ISAAC Phase One have been listed on page 75 of this Manual and coded. Please use the codes provided. If your language is not listed, please contact Tadd Clayton, Data manager, IIDC for a code number to be issued (contact details page 93).

An example of how these codes can be inserted into the questionnaire is shown on page 72–73 as well as more details on the use of the 'office use only' boxes.

15. Coding and Data Transfer Section

15.1 Introduction

The purpose of this section is to describe in detail how ISAAC Phase Three data should be formatted and structured when it is sent to the ISAAC Phase Three International Data Centre (IIDC) in Auckland, New Zealand.
The data may be sent via a range of media (e.g. 3.5 inch diskette, CD-ROM, email) but must be sent as computer files, not on paper forms. It is the responsibility of the principal investigator to arrange for the data to be entered onto a computer. The IIDC does not have the resources to carry out this task for any centres.

As noted in section 6, page 24, double entry of data should be used to minimise data entry errors. Double entry of data, as the name suggests, involves entering the data once, followed by a second entry of the data which is compared with the first version to identify any keystroke errors. Data entry computer software and some other software (e.g. Epi Info) will allow the user to compare the first and second versions of the data as the operator is entering the data for the second time. Any discrepancies between the first and second versions can immediately be resolved using the paper questionnaire as a reference.

Please retain the paper questionnaires in secure storage for a minimum period of 3 years following data entry. The questionnaires must be available during the data checking process for checking against the computer record. In some countries it may be a condition of ethical approval for the study that the paper questionnaires are stored for a specific period of time.

The answers to the questions provided by the child or parent should be entered onto the computer exactly as they responded. No corrections should be made to remove apparent inconsistencies between the responses to different questions. Corrections may be made to errors in the demographic information if the correct information is available from another source (i.e. the school). However, all corrections to demographic information should be made to a copy of the original data file(s). Please retain copies of the original and any amended versions of the data file(s) for a minimum period of 3 years as a safeguard against accidental loss of the data.

The preferred operating systems for computer files sent to the IIDC on 3.5 inch diskette or CD-ROM are Microsoft Windows or MS-DOS. However, if principal collaborators do not have access to computers using one of these operating systems, the IIDC can convert files from Macintosh and UNIX formats.

The data format described in this section applies to the data sent to the IIDC, not necessarily to the data held locally. The structure required of the data when being sent to the IIDC certainly can be used as the local data format but it is not necessary to do so. The locally held data must be able to be transcribed to the format given in this manual. To do this each of the responses for each question required to be sent to the IIDC must have a unique code in the local data set so that they can be translated to the appropriate IIDC code.

Data for questions that have been added to the ISAAC Phase Three core questionnaires to address local research hypotheses are not required by the IIDC. Only the questions of the Phase Three core questionnaires are included in this manual and only the data from these questions should be sent to the IIDC.

If the data is sent to the IIDC on 3.5 inch diskette or CD-ROM, the disks need to be identified

clearly. This identification is achieved using a label attached to the disk and a file on the disk containing identifying information. This file is known as the DATA HEADER. The DATA HEADER file should also be included if the data is sent via email. The structure and content of the DATA HEADER is described in detail below.

The data for a centre is sent as one or more DATA files[a] and these files also need to be clearly identified. Each DATA file is identified by a one-line record at the beginning that gives information about that file. This single record at the beginning of each DATA file is called the FORM HEADER. The structure and content of the FORM HEADER is described in detail below.

As an additional check, each data record has identification information contained within it. This is the information on form type, form version, country and centre of survey.

There is clearly considerable redundancy involved in all this identification material but it is absolutely essential that the data received by the IIDC is unambiguous and the redundancy allows checks to be made.

A single form will be used to format the data sent to the IIDC. For ISAAC Phase One the Phase One Coding and Data Transfer Manual described 6 forms that could be used to transfer the data, either in segments or as a single record. In practice, few if any centres chose to send the data in segments and the IIDC has decided to define only a single form for Phase Three. If any centres would prefer to send data in another format they should contact the IIDC before formatting or sending any data.

The IIDC prefers that all data files are saved in plain text format using the structure described in this section. However, some centres may not be familiar with text format data files (also known as 'flat' files) and may prefer to send the data in a spreadsheet or database file format. If this is the case, the principal collaborator should contact the IIDC to confirm that the IIDC can read the intended format. File formats that the IIDC can accept include Microsoft Excel, Microsoft Access, Lotus 1-2-3, Paradox, Dbase, Quattro Pro, Microsoft Works and Epi-Info. If one of these file formats is used to send data to the IIDC, please follow the data structure described in this section as closely as is feasible. Any alterations to the order of variables, variable names or format of variables described in this section should be clearly described in correspondence to the IIDC.

The item Name used in the manual is the name used by the IIDC to identify that data item (usually called a variable) in computer files. The Columns indicate the columns, numbered from 1 at the left margin, in which the code for the variable is to appear in the data file. Data for different subjects (children or respondents) must be written in different records (lines).

Blank spaces are not allowed in the DATA file records (except in the DATA HEADER file). Leading zeros are to be used where necessary to pad fields to avoid blanks. Use the code '9' to indicate that there was no response from the respondent. No response may occur deliberately because it was a question that was not required to be answered, or the respondent chose not to answer the question, or may occur unintentionally because the respondent did not correctly supply the information.

COUNTRY codes have been issued by the IIDC. The IIDC and the ISAAC Regional Coordinators

[a] A data file is a collection of data records, each occupying one line. A data record is the information obtained about one subject, and is sometimes called a data form, or an observation.

will issue CENTRE codes as necessary when Centres register and are accepted into the study. Principal collaborators should contact the IIDC or their Regional or National Coordinator if they do know their CENTRE code. Centres that participated in Phase One will continue to use their Phase One CENTRE and COUNTRY code.

SCHOOL and SERIAL codes must be unique within each Centre and are to be allocated by the Centre. Centres may choose to allocate SERIAL codes for subjects (children) consecutively within the centre, or they may wish to re-start the numbering for each school. Either approach is acceptable as long as no two (or more) respondents share the same combination of SCHOOL and SERIAL codes within a centre. The IIDC may wish to discuss the data for individual respondents during the data checking process. Centres are therefore advised to adopt a numbering system that allows them to easily associate a record in the computer file with a paper questionnaire.

15.2 Methods of Data Transfer

Media that may be used to transfer data files to the IIDC include 3.5 inch diskette and CD-ROM sent via post, and email. At present the IIDC does not have the capability to accept other formats such as Iomega Zip or Jaz disks, DVD or tape. Please contact the IIDC prior to data transfer if you would prefer to use these or other formats. The IIDC may also accept data files via file transfer protocol (ftp). Please contact the IIDC if you would prefer to use this method.

15.2.1 Diskette and CD-ROM

As stated above, diskettes and CD-ROMs should be written on an MS-DOS or Microsoft Windows computer. If such a computer is not available, please clearly state the name and version number of the relevant operating system in correspondence with the IIDC and on the disc label. If at all possible, please avoid using computers with country or region specific operating systems.

The version of the data should be numbered sequentially from 01. The first copy of the data sent to the IIDC will be version 01. If, during correspondence with the IIDC, changes are made to the data and a further version of the data is sent to the IIDC, this will be version 2 and so on.

Each diskette or CD-ROM must contain at least two files: a DATA HEADER file and one or more DATA files.

DATA HEADER file: The DATA HEADER file contains information about the person preparing the disk and the data files included on the diskette.

Name the DATA HEADER file as "`Hmmmnn.rrr`", where:
`mmm` is the ISAAC country code number,
`nn` is the two digit data version number, and
`rrr` is the ISAAC centre code number.
For example, the first DATA HEADER from Auckland (CENTRE 001), New Zealand (COUNTRY 001) will be called `H00101.001`

DATA files: The first line of every DATA file should be the FORM HEADER. The FORM HEADER should be followed by the actual data, one line for each subject (participant), using the structure described in the data form (see section 15.4).

The data files should be named as "Dxxmmmnn.rrr", where:

xx is any number identifying the DATA file on the diskette or CD-ROM,

mmm is the ISAAC country code number,

nn is the two digit data version number, and

rrr is the ISAAC centre code number.

For example, the first DATA file from Auckland (CENTRE 001), New Zealand (COUNTRY 001) will be called D0100101.001

Diskettes or CD-ROMS should, if possible, be sent to the IIDC via registered mail. The IIDC will acknowledge receipt of data within one working day (except for holiday periods) by return mail and fax or email if a fax number or email address has been supplied. If a centre has received no response from the IIDC two weeks after the data has been sent, please contact the IIDC by fax or email to request confirmation that the data has been received.

15.2.2 Email

Data files may be sent as attachments to email messages. All email with data attachments should be sent to Tadd Clayton: t.clayton@auckland.ac.nz.

Each email message must contain at least two attached files: a DATA HEADER file and one or more DATA files.

The DATA HEADER and DATA files should include the same information and be named in the same manner as those described in section 15.2.1.

The IIDC will acknowledge receipt of the data. If no response has been received from the IIDC two weeks after the data has been sent, please contact the IIDC by fax or email requesting confirmation that the data has been received.

15.3 Labels and Headers

15.3.1 Disk Label

Every data diskette or CD-ROM sent from the ISAAC centre to the IIDC must have a DISK LABEL affixed to it. The DISK LABEL should include the following information:

ISAAC country number
ISAAC centre number
Date when the disk was written (format as DDMMYYYY)
Data version number
Data type
Operating system name and version number

An example of a DISK LABEL:

COUNTRY:	001
CENTRE:	001
Date:	15/07/2001
Data Version:	02
Data type:	Phase Three
Operating System:	Windows NT Workstation
OS Version:	4

This shows that:

- It is from COUNTRY 001 (New Zealand)
- It is from CENTRE 001 (Auckland)
- It was written on 15 July 2001
- It is version 2 of the data from Auckland
- The data is from an ISAAC Phase Three study
- It was written using version 4 of the Windows NT Workstation operating system

15.3.2 Data Header

The DATA HEADER file contains ten lines plus one line for every data file included on the disk. Details of each line are shown in the table below:

Line	Name	Specification and Codes		Columns
1	FORM	Identifies that this is a DATA HEADER	HDISAAC	1 to 7
1	VERSION	DATA HEADER version	2	8
2	NAME	Name of person to be contacted regarding the contents of the disk.		1 to 255
3	ADDRESS	Address of person to be contacted regarding the contents of the disk.		1 to 255
4	PHONE	Telephone number, fax number and email address of the person to be contacted regarding the contents of the disk.		1 to 255
5	DWRITTEN	Date of writing the disk (ddmmyyyy)		1 to 8
6	COUNTRY	ISAAC Country code number		1 to 3
7	CENTRE	ISAAC Centre code number		1 to 3
8	DVERSION	Data version identification number The ISAAC centre must give a sequential data version number to each different version of the data that is submitted to the IIDC. The number of the first version should be 01, the second should be 02, etc. The data version number is recorded in the DATA HEADER, and also on the DISK LABEL. This number is also part of the names of the DATA HEADER and the DATA files.		1 to 2
9	TOTFILE	Total number of files on the diskette, CD-ROM or attached to the email message. Record here the total number of files on the diskette,		1 to 3

		CD-ROM or attached to the email message. This number will be 1 (for the DATA HEADER) plus the number of DATA files on the disk.		
10	PHASE3	A code to identify that the data is from an ISAAC Phase Three study.	3	1
11 -		One line for each data file. The line will consist of the filename, the form type the file contains and the number of records within the file.		
	DATAxx	Data file name using the format `Dxxmmmnn.rrr` where: `xx` is a unique identifier, `mmm` is the ISAAC country number, `nn` is the last two digits of the data version number (DVERSION), and `rrr` is the ISAAC centre number		1 to 12
	blank			13 to 15
	FORMxx	Type of form within the data file. This will always be `07` unless otherwise agreed with the IIDC.		16 to 17
	blank			18 to 20
	NUMRECxx	Number of data records within the data file. DATAxx, FORMxx and NUMRECxx are repeated as many times as is necessary to describe all the data files on the disk.		21 to 26

An example of a DATA HEADER:

```
HDISAAC2
Tadd Clayton
Department of Paediatrics, University of Auckland, Private Bag 92019, Auckland,
     New Zealand.
Ph: +64 9 373 7599x6451, Fax: +64 9 373 7602, Email: t.clayton@auckland.ac.nz
27/08/2000
001
001
01
004
3
D0100101.001  07  000435
D0200101.001  07  000416
D0300101.001  07  002516
```

This shows that:

- The file is a DATA HEADER (version 2)
- It was prepared by Tadd Clayton
- It was written on 27 August 2000
- It is from COUNTRY 001 (New Zealand)
- It is from CENTRE 001 (Auckland)
- It is version 1 of the data
- There are 4 files on the diskette, CD-ROM or attached to the email

- The data is from an ISAAC Phase Three study
- There are three data files containing data on 435 subjects, 416 subjects and 2,516 subjects respectively

Note that the line containing the address information and the line containing the telephone, fax and email information have wrapped to a second line in this example. In the actual DATA HEADER each would occupy a single line of up to 255 characters.

15.3.3 Form Header

The FORM HEADER is the first line of information in each text format data file. If a centre sends the data as a spreadsheet, the FORM HEADER should occupy the top left cell of the spreadsheet with the remaining cells on the first row left blank. If a centre sends the data as a database file, the FORM HEADER should be omitted from the file but the information contained in the FORM HEADER, including identification of the file to which it applies, should be included in correspondence to the IIDC.

The FORM HEADER includes the following information:

Name	Specification and Codes		Columns
FORM	Identifies that this is a FORM HEADER	HDRFORM	1 to 7
VERSION	FORM HEADER version	2	8
HDFORM	Form identification of the following forms	07	9 to 10
HDVERSN	Form version of the following forms	1	11
HDNMFRM	Number of records of type HDFORM in this file		12 to 17
PHASE3	Identifies that the data is from an ISAAC Phase Three study	3	18

None of the characters in the FORM HEADER should be left blank.

HDFORM is the code that identifies the form used to structure the data in the file. For all ISAAC Phase Three data this will be `07` unless the principal collaborator and the IIDC have agreed to use a different, centre specific form.

The number of records (HDNMFRM) included in the FORM HEADER should be consistent with the number of records included in the DATA HEADER for the data file.

An example of a FORM HEADER:

```
HDRFORM20710025573
```

This shows that:

- This is a FORM HEADER
- This is version 2 of the FORM HEADER
- The DATA file uses version 1 of FORM 07 to structure the data
- The DATA file contains 2557 records
- The data in the DATA file is from an ISAAC Phase Three study

15.4 Coding of Data

PHASE THREE DATA COLLECTION

ALL QUESTIONNAIRE DATA

Form: 07
Version 1

Item	Name	Specification and Codes		Columns
1	FORM	Questionnaire type 07 = All questionnaire data	THIS IS FORM TYPE 07 CODE 07 HERE	1 to 2
2	VERSION	Form version	1	3
3	COUNTRY	ISAAC Country code		4 to 6
4	CENTRE	ISAAC Centre code		7 to 9
5	AGEGRP	Age group of the children / respondents 06 = 6 and 7 year old children 13 = 13 and 14 year old respondents		10 to 11
6	SCHOOL	School identification number		12 to 15
7	SERIAL	Serial number of respondent		16 to 22
8	DINT	Date of interview / receiving response Use ddmmyyyy where: dd = Day mm = Month yyyy = Year Use code 99 or 9999 if information is not available for any of these components		23 to 30
9	AGE	The actual age of the child / respondent (years) Use code 99 for an invalid response		31 to 32
10	DBIRTH	Date of birth of the child / respondent Use ddmmyyyy where: dd = Day mm = Month yyyy = Year Use code 99 or 9999 if information is not available for any of these components		33 to 40
11	SEX	Sex of the child / respondent 1 = Male 2 = Female		41

		9 = Any other response	
12	LANGUAGE	Language of the questionnaire Use a three digit code for each language used in the centre from the list on page 75. If an appropriate language code is not available, please contact Tadd Clayton at the IIDC (contact number page 93) to request a code number for your language.	42 to 44
13	WHEZEV	Has your child / Have you ever had wheezing or whistling in the chest at any time in the past? 1 = Yes 2 = No 9 = Any other response	45
14	WHEZ12	Has your child / Have you had wheezing or whistling in the chest in the past 12 months? 1 = Yes 2 = No 9 = Any other response	46
15	NWHEZ12	How many attacks of wheezing has your child / have you had in the past 12 months? 1 = None 2 = 1 to 3 3 = 4 to 12 4 = More than 12 9 = Any other response	47
16	AWAKE12	In the past 12 months, how often, on average, has your (child's) sleep been disturbed due to wheezing? 1 = Never woken with wheezing 2 = Less than one night per week 3 = One or more nights per week 9 = Any other response	48
17	SPEECH12	In the past 12 months, has wheezing ever been severe enough to limit your (child's) speech to only one or two words at a time between breaths? 1 = Yes 2 = No 9 = Any other response	49
18	ASTHMAEV	Has your child / Have you ever had asthma? 1 = Yes 2 = No 9 = Any other response	50
19	EXWHEZ12	In the past 12 months, has your (child's) chest sounded wheezy during or after exercise? 1 = Yes 2 = No	51

9 = Any other response

20	COUGH12	In the past 12 months, has your child / have you had a dry cough at night, apart from a cough associated with a cold or chest infection? 1 = Yes 2 = No 9 = Any other response	52
21	PNOSEEV	Has your child / Have you ever had a problem with sneezing or a runny or blocked nose when he / she / you DID NOT have a cold or the flu? 1 = Yes 2 = No 9 = Any other response	53
22	PNOSE12	In the past 12 months, has your child / have you had a problem with sneezing or a runny or blocked nose when he / she / you DID NOT have a cold or the flu? 1 = Yes 2 = No 9 = Any other response	54
23	IEYES12	In the past 12 months, has this nose problem been accompanied by itchy-watery eyes? 1 = Yes 2 = No 9 = Any other response	55
24	PNOSE<mth>	In which of the past 12 months did this nose problem occur? 1 = No nose problem in month 2 = A nose problem in month 9 = Any other response PNOSEJAN 56, PNOSEFEB 57, PNOSEMAR 58, PNOSEAPR 59 PNOSEMAY 60, PNOSEJUN 61, PNOSEJUL 62, PNOSEAUG 63 PNOSESEP 64, PNOSEOCT 65, PNOSENOV 66, PNOSEDEC 67	56 to 67
25	IACTIV12	In the past 12 months, how much did this nose problem interfere with your (child's) daily activities? 1 = Not at all 2 = A little 3 = A moderate amount 4 = A lot 9 = Any other response	68
26	HFEVEREV	Has your child / Have you ever had hayfever? 1 = Yes 2 = No 9 = Any other response	69

27	RASHEV	Has your child / Have you ever had an itchy rash which was coming and going for at least six months? 1 = Yes 2 = No 9 = Any other response	70
28	RASH12	Has your child / Have you had this itchy rash at any time in the past 12 months? 1 = Yes 2 = No 9 = Any other response	71
29	SITESEV	Has this itchy rash at any time affected any of the following places: the folds of the elbows, behind the knees, in front of the ankles, under the buttocks, or around the neck, ears or eyes? 1 = Yes 2 = No 9 = Any other response	72
30	RASHAGE	At what age did this itchy rash first occur? 1 = Under 2 years 2 = Age 2-4 years 3 = Age 5 or more 9 = Any other response *(Code 9 for the 13-14 year olds questionnaire)*	73
31	RCLEAR12	Has this itchy rash cleared completely at any time during the past 12 months? 1 = Yes 2 = No 9 = Any other response	74
32	RAWAKE12	In the past 12 months, how often on average, has your child / have you been kept awake at night by this itchy rash? 1 = Never in the past 12 months 2 = Less than one night per week 3 = One or more nights per week 9 = Any other response	75
33	ECZEMAEV	Has your child / Have you ever had eczema? 1 = Yes 2 = No 9 = Any other response	76

Code 9 for the following 15 variables (items 34 to 48) if the child / respondent has not seen the video questionnaire. This will always be the case for the 6-7 year old participants.

34	BRTHEV	Has your breathing been like this at any time in your life? 1 = Yes 2 = No 9 = Any other response	77
35	BRTH12	Has your breathing been like this in the past year? 1 = Yes 2 = No 9 = Any other response	78
36	BRTH1M	Has your breathing been like this one or more times a month? 1 = Yes 2 = No 9 = Any other response	79
37	EXBRTHEV	Has your breathing been like the boy's in the dark shirt following exercise at any time in your life? 1 = Yes 2 = No 9 = Any other response	80
38	EXBRTH12	Has your breathing been like the boy's in the dark shirt following exercise in the past year? 1 = Yes 2 = No 9 = Any other response	81
39	EXBRTH1M	Has your breathing been like the boy's in the dark shirt following exercise one or more times a month? 1 = Yes 2 = No 9 = Any other response	82
40	WWOKENEV	Have you been woken like this at night at any time in your life? 1 = Yes 2 = No 9 = Any other response	83
41	WWOKEN12	Have you been woken like this at night in the past year? 1 = Yes 2 = No 9 = Any other response	84
42	WWOKEN1M	Have you been woken like this at night one or more times a month? 1 = Yes	85

		2 = No 9 = Any other response	
43	CWOKENEV	Have you been woken like this at night at any time in your life? 1 = Yes 2 = No 9 = Any other response	86
44	CWOKEN12	Have you been woken like this at night in the past year? 1 = Yes 2 = No 9 = Any other response	87
45	CWOKEN1M	Have you been woken like this at night one or more times a month? 1 = Yes 2 = No 9 = Any other response	88
46	SABRTHEV	Has your breathing been like this at any time in your life? 1 = Yes 2 = No 9 = Any other response	89
47	SABRTH12	Has your breathing been like this in the past year? 1 = Yes 2 = No 9 = Any other response	90
48	SABRTH1M	Has your breathing been like this one or more times a month? 1 = Yes 2 = No 9 = Any other response	91

16. Expression of interest

In order to assist our forward planning, it would be most helpful if you could fax or email, the form on the next page, to the International Data Centre in Auckland, indicating whether your centre intends to take part in Phase Three. We are not seeking a firm decision at this stage, simply a declaration of interest. However, it would be helpful to know which centres are definitely **not** interested, as well as those which are. Therefore, as with all ISAAC surveys, we trust the response rate will be high!

If you have not previously conducted a study with ISAAC but wish to register your interest in conducting one in the future we welcome your interest.

The ISAAC Steering Committee

ISAAC International Data Centre
Department of Paediatrics
University of Auckland
Private Bag 92019
Auckland, New Zealand

Phone: +64 9 373 7599 x 6451
Fax: +64 9 373 7602
Email: p.ellwood@auckland.ac.nz
http://isaac.auckland.ac.nz

Note: Please complete and fax or email the following form only if you have not already done so.

16.1 Expression of Interest form

Please complete and return to the **ISAAC International Data Centre:**

Fax: +64 9 373 7602 or ***Email to: p.ellwood@auckland.ac.nz***

ISAAC Phase Three - Expression of Interest

This form may also be used to register centres who have not previously conducted an ISAAC Study

My centre is interested in taking part in ISAAC Phase Three	Yes ☐	No ☐	Don't know ☐
My centre could complete Phase Three with local funding	Yes ☐	No ☐	Don't know ☐
My centre would definitely require outside funding for Phase Three	Yes ☐	No ☐	Don't know ☐

Centre name:	
Country:	
Principal Investigator: (one per centre)	
Phone:	
Fax:	
Email:	
Postal Address:	

17. Registration Document

Instructions

1. Please complete the ISAAC Registration Document to register as an ISAAC Phase Three Centre

2. **If insufficient space has been provided, please use an appropriately numbered continuation page.**

3. Once completed, please return the Registration Document to your ISAAC Regional Coordinator. Retain a copy for your records and send a copy to the ISAAC International Data Centre (IIDC):

Address: Philippa Ellwood, IIDC, Division of Paediatrics, Faculty of Medicine and Health Science, University of Auckland, Private Bag 92019, Auckland New Zealand. Or fax to: 64 9 3737602

ISAAC Region: _____

Regional Coordinator: _____

Country Name: _____	**Country Number:** _____
Centre Name: _____	**Centre Number:** _____

1. Date of Completion: _____

2. Principal Investigator details:

Name: _____

Position: _____	Institution: _____

Address: _____ Telephone: _____

_____ Fax: _____

_____ E-mail: _____

_____

3. Other main collaborators (Names, addresses and role)

_____
_____
_____
_____
_____
_____
_____
_____

Please state the name of the person who will be the person that the IIDC communicates with regarding the study.

4. Basic details of the planned ISAAC Phase Three study

a) Questionnaire to the 13/14 year olds (Compulsory 3 core questionnaires on asthma, rhinitis and eczema) Yes ☐ No ☐

b) Video questionnaire (International version) (Strongly recommended) Yes ☐ No ☐

c) Questionnaire to parents of 6/7 year olds (Strongly recommended) Yes ☐ No ☐

d) Are you planning to add other assessments to your ISAAC Protocol? Yes ☐ No ☐

If YES, please provide brief details and send a copy of the questionnaires to the IIDC.

5. Have there been prevalence studies of asthma, allergic rhinoconjunctivitis, atopic eczema, or other respiratory disease (particularly concerning children) in the chosen study area within the last 10 years? Yes ☐ No ☐

If yes please give brief details

6. Declaration

I agree to undertake the ISAAC Phase Three study in the manner described in the ISAAC Manual.

Name: _____	
Signature: _____	Date: _____

18. Centre Report

The Centre Report is an important document, designed to assist each ISAAC Phase Three centre and the ISAAC International Data Centre (IIDC) to accurately document centre methodology. The following notes may be of assistance when the attached Centre Report is being completed. We encourage you to contact the ISAAC International Data Centre if there is any thing that is unclear.

We advise collaborators to read the Centre Report through when you receive it, as there may be questions that you can answer as Phase Three progresses. We recognise that the meaning of some of the questions contained in the Phase One report were difficult to understand and have tried to rectify this.

Questions

1.3	A map of the area or city, with the ISAAC boundaries drawn in will allow us to make a direct comparison with the area used for ISAAC Phase One.
1.4 – 1.8	It is important to document the reasons why schools are excluded and the reasons why collaborators reject schools after they have been selected. Some schools are excluded before the sampling frame has been set and some schools are rejected by the researchers after they have agreed to take part.
1.9	This question has 2 parts. Part A asks for the total number of schools in the sampling frame that was chosen and Part B asks for the number of children for the selected age group that were in these schools.
2.1	Centres may use different methods of selecting children within schools: grade/level/year where the classes with most children in the age group are selected to participate; age group where only children in the age group, regardless of grade/level/year are selected to participate; and other methods, that may include elements of these two methods.
3.1 – 3.4	Double entry of data is the expected method of entering data, to minimise data entry errors. If the data has not been double entered a detailed explanation of method employed and quality checks are necessary.
4.1 – 4.8	Collaborators are encouraged to check the demographic details on the questionnaires and amend if necessary. For example a pupil may have inserted the wrong birth date - this can be corrected using the information obtained from the school. **All changes must be documented**. It is not permissible to change any other data. All data must be entered into the computer as given in the questionnaire and original data submitted to the IIDC.
5.1 – 5.6	These questions allow us to calculate the response rate and the participation rate of the schools and pupils. The answers to questions 5.5 and 5.6 will add up to the answer you gave for question 5.2.
6.1 – 6.3	Any translations of the English language questionnaire should have a uniform approach. If centres use a translation already developed, the IIDC would like to know. The video questionnaire is strongly recommended. If there are any problems, we would like to know about them.

Thank you for reading and completing this report. The IIDC will be able to produce accurate details for future publications.

Innes Asher *Tadd Clayton* *Philippa Ellwood*

Alistair Stewart *Ed Mitchell*

ISAAC International Data Centre, Phone: 64 9 3737599 extension 6451, Fax: 64 9 3737602

Email: p.ellwood@auckland.ac.nz *t.clayton@auckland.ac.nz*

18.1 Example ISAAC Phase Three 13/14 yr age group Centre Report

Country Name: _____ Country/Centre Number: _____

Centre Name: _____ Age group: _____

Principal Investigator: _____ Date of Phase Three data collection: _____

National Coordinator: _____ Date report completed: _____

Regional Coordinator: _____ Local ethical approval granted: Date: _____

Name of Ethics Committee: _____

1. SAMPLING FRAME AND SCHOOLS

1.1 Which of the sampling frame categories is most appropriate for your study?:
Note: The sampling frame is the geographic area from which the schools were selected, as well as other criteria that defines which schools were available for selection for Phase 3.
Please tick the box that best describes your sampling frame:

Geographic area only	☐
Geographic area and specific school type	☐
Geographic area and specific ethnic group	☐
Geographic area and specific language	☐
Other (please specify below)	☐

1.2 Please describe the sampling frame for your centre:
Note: Please use similar terms to those in these examples: "All schools in the Auckland area; Some schools in the Western Health District"; "Private schools in the Canterbury region".

1.3. Have you sent a detailed map showing the boundaries of your Phase Three centre to the ISAAC International Data Centre (IIDC)? Yes ☐ No ☐
Note: A commercially available map of your city and environs with the ISAAC boundaries clearly marked with pen would be ideal.

1.4 Were any schools excluded from the sampling frame before being approached to participate? For example, schools might be excluded if the researchers know that they are located in areas with difficult access or if the children are unable to participate. These schools would then be left out of the sampling frame and not included in the selection process. Yes ☐ No ☐

1.5 If yes, please give your reasons why these schools were excluded from the sampling frame.

1.6 Did you reject any schools after they had been selected? Yes ☐
For example a school may have elected to participate and you then found that the students were unable to complete the questionnaire because they were disabled. No ☐

1.7 Please give your reasons why you rejected these schools.

1.8 How many students (of your selected age group) were there in the rejected schools? _____

1.9 Please give: A - The total number of schools (for this age group) in your selected sampling frame? _____

B - The total number of children (for this age group), that were in the schools in the sampling frame? _____

1.10 Did you approach all schools (for this age group) in your sampling frame? Yes ☐ No ☐

If No:

1.11 Were the schools selected using a random sampling method? Yes ☐ No ☐

1.12 Was there stratification by school type, followed by random sampling of schools? For example, you may have stratified the population according to whether they attend public or private schools. Yes ☐ No ☐

1.13 If the schools were not selected using a random sampling method, please describe the method used.

2. CLASSES AND CHILDREN

2.1 Which overall approach did you use when selecting children within the schools?
Please refer to attached notes for clarification.

- Grade/level/year? ☐
- Selection by age group? ☐
- Other? ☐

2.2 If you answered 'Other' for question 2.1 please describe your approach to selecting children within the schools:

2.3 Which children were selected from the grade/level/year **or** age group?

- All Children ☐
- Some children ☐

2.4 If you answered 'some children' to question 2.3 please describe how these children were selected.

2.5 How many grades/levels/years **or** years of age did you select?

- One ☐
- Two ☐
- Other ☐

2.6 If you answered 'other' to question 2.5 please describe how many grades/levels/years **or** years of age you selected.

3. DATA ENTRY

3.1 Was the data double entered?

- Yes ☐
- No ☐

Double entry is a common method of data entry that minimises data entry errors and is the expected method of data entry for ISAAC. The data is entered two times, preferably by two different people. the two versions of the data set are compared and any differences checked against the original questionnaire.

If you answered 'YES' please go to question 4.

3.2 If you answered 'NO' to question 3.1, please describe the data entry method you used.

3.3 If you answered 'NO' to question 3.1 can you check (and/or have you checked) the data for entry errors? Yes ☐ No ☐

If you answered 'YES' to question 3.3

3.3A Please describe your method for checking for data entry errors.

4. CHANGES TO DATA AFTER DATA ENTRY

4.1 Were any changes made to the demographic data after the questionnaires were completed? Yes ☐ No ☐

The demographic data is the information concerning the age, sex, date of birth and date of interview for each child. You may have changed this data if there was incorrect information written and you had checked this against the information available from the school. You may also have made corrections at the request of the International Data Centre.

4.2 If you answered yes to question 4.1, please describe the changes made to the demographic data.

4.3 Were any changes made to the data from the asthma, rhinitis, eczema or video questionnaires? Yes ☐ No ☐

If you answered 'NO' to question 4.3, please go to question 5, participation rates

4.4 If you answered '***YES'*** to question 4.3, were these changes due to data entry error? Yes ☐ No ☐

If you answered 'YES', to question 4.4, please go to question 5, participation rates.

4.5 *If No:* Please describe the reasons why you changed the data.

4.6 What percent of the observations had changes made to the asthma, rhinitis, eczema or video questionnaire? _____

4.7 Can the data be returned to its original form? Yes ☐ No ☐

4.8 Has a copy of the data without the changes been submitted to the IIDC? Yes ☐ No ☐
(if '***NO***' could you please send a copy to the IIDC)

4.8 Have you kept a copy of the data without the changes? Yes ☐ No ☐

5. PARTICIPATION RATES

5.1 How many schools participated in the ISAAC Study in your centre? _____

5.2 What was the total number of children selected to participate in these schools? _____

5.3 Did you include children younger and older than the age group? Yes ☐ No ☐

5.3A. Has the data from these children been included in the data submitted to the IIDC? Yes ☐ No ☐

5.3B. If NO, is this data available on request by the IIDC? Yes ☐ No ☐

5.4 How many schools refused to participate after they had been selected? _____
(answer 0 if no schools refused to participate).

5.4A. How many students of your selected age group were there in the schools that refused to participate? _____

5.5 What is the total number of students that participated? This will be the same number as in the data that has been submitted to the IIDC. _____

5.6 How many students (or parents) did not participate? This answer and the answer to question 5.5 should add up to the number you gave for question 5.2. _____

5.7 Did you have any difficulties getting the number of children that you needed for the required participation rate? Yes ☐ No ☐

If Yes – What difficulties did you encounter?

6. TRANSLATION OF QUESTIONNAIRES

6.1 Did you use the English language questionnaire for this age group? Yes ☐ No ☐

6.2 Did you use any translations of the English language questionnaire for this age group? Yes ☐ No ☐

If you answered 'NO' please go to question 7

6.3 How many languages were used in your centre for this age group? _____

6.4 Please name the languages that you used for this age group.

6.5 Did you develop the translation/s in your centre? Yes ☐ No ☐

6.5A. If No, where did you obtain these? Centre Name: _____
Collaborators Name _____

Now, please go to question 7

6.6 If yes, was the translator familiar with asthma and allergy terminology? Yes ☐ No ☐

6.7 Were the local community approached to help with difficult words and concepts? Yes ☐ No ☐

6.8 Were other centres in the country or region involved in preparation of the translated questionnaires? Yes ☐ No ☐

6.9 If you answered Yes to question 6.8, please list the other centres.

6.10 Were the translated questionnaires translated back to English by an independent translator? Yes ☐ No ☐

6.11 Were the translated questionnaires pilot tested? Yes ☐ No ☐

6.12 Has a copy of the translation been sent to the IIDC? (If a copy has not yet been sent, we would appreciate receiving a copy). Yes ☐ No ☐

6.13 Could you please give the proportion of questionnaires that were used in each language?

%	Language

7. VIDEO (For older age group only)

7.1 Did you use the international video in all the secondary schools that you went to? Yes ☐ No ☐

7.1.1 If No, please give the reasons why it was not used.

7.2 How many schools did the video questionnaire? _____

7.3 How many schools did NOT do the video questionnaire? _____

7.4 How many children completed the video questionnaire? _____

7.5 What spoken language(s) was (were) used for the video questionnaire? (please specify)

8. Additional questions

8.1 Did you use additional questions following the Core ISAAC questions for either age group? Yes ☐ No ☐

If yes could you please send a copy of these questions to the IIDC.

Thank you for completing this report. This will enable the ISAAC International Data Centre (IIDC) to accurately document the methodology for each centre for the analysis and writing of manuscripts. The IIDC would appreciate this Centre Report being returned to the IIDC by either fax 64 9 3737602 or by post. We will enter the details into our database and send you a completed copy for you to check and keep for your records.

Best wishes from Innes Asher, Tadd Clayton, and Philippa Ellwood.

ISAAC International Data Centre

Department of Paediatrics, University of Auckland, Private Bag 92019, Auckland, New Zealand.

Email: p.ellwood@auckland.ac.nz or t.clayton@auckland.ac.nz

Phone 64 9 3737599 extension 6451, Fax 64 9 3737602

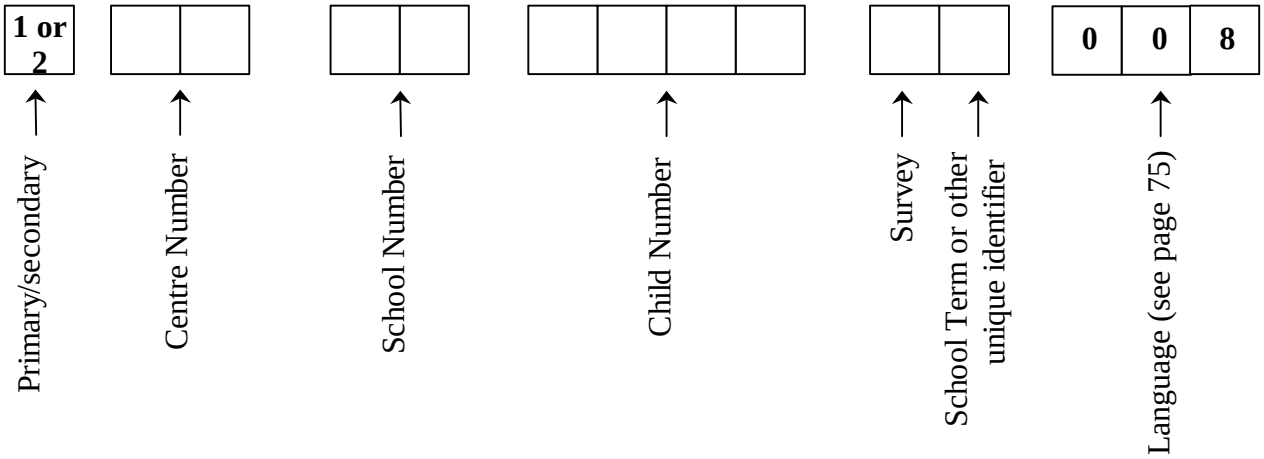
We would welcome further comment regarding any difficulties that you encountered

19. Detailed Guidelines for fieldworkers

The following detailed guidelines are intended to assist the fieldworker to implement the survey. They are a guide only as it is recognised that each centre is unique and faces different situations and problems. We hope that they may be useful for some centres.

19.1 Identifying Boxes 'For Office Use Only'

In New Zealand, for Phase One, to identify the age group, centres, schools, children, survey number school term and language used, an 'office use only' set of boxes was designed. These boxes were placed at the top right hand side of the front page (example page 74) and ensured that each student, school and centre had a unique number when entering data into a computer.



The primary school questionnaires has a **1** pre-printed in the first box. The secondary school questionnaires has a **2** pre-printed in the first box. The language is coded as per page 75 (e.g. 008 for English, 043 for Xhosa). Other boxes were completed by the fieldworker.

The student number and survey number should be entered before the questionnaires are handed out to the children and recorded on the school lists. The six New Zealand centres were numbered as follows:

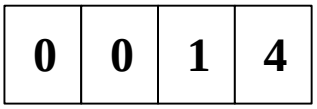
CENTRE:
1 = Auckland
2 = Wellington
3 = Christchurch
4 = Hawke's Bay
5 = Nelson
6 = Bay of Plenty

SCHOOL:
Enter a unique number between 1 and 99 for each sampled school in each centre. Numbers can be repeated for primary and secondary schools as each form type can be identified by the **1** or **2** in the first box. Start number units the in the right hand box.

0	**2**

Example

CHILD:
Enter a unique number from 1 for each sampled child in each school. Start number units in the right hand box. For each school numbering can begin from 1or continue on from school to school



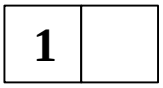
Example

SURVEY:

Enter **1** in the first box for the first send out.

Enter **2** in the first box for the second send out

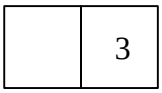
The second box is for the School Term or other identifying mark.



Example

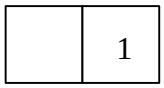
TERM:

The second box, next to the survey number is used for the School Term that the survey was carried out in. This box could also be used to record some other method of identifying the time of year, such as season.



= Term 3 2001

Example

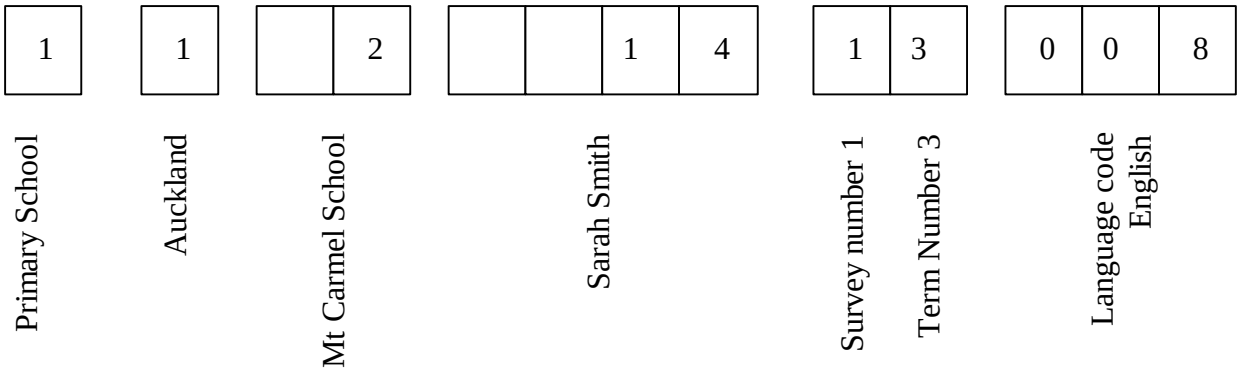


= Term 1 2002

Example

As the students names were not entered onto the computer, the numbers in these boxes proved to be a successful way of keeping track of each questionnaire. The numbers were entered alongside the students name on the class lists and proved a successful tracking method when a questionnaire needed checking at a later date.

Office use only



19.2 Example New Zealand questionnaire

NEW ZEALAND SURVEY OF BREATHING, NOSE AND SKIN PROBLEMS
QUESTIONNAIRE FOR SECONDARY SCHOOL STUDENTS

Office Use Only [2] [ ] [ ][ ] [ ][ ][ ][ ] [ ][ ]

Instructions for completing the questionnaire

On this sheet are questions about your name, school and birth date. Please write in your answers to these questions in the space provided.
All other questions require you to TICK your answer in a box. If you make a mistake put a cross in the box and tick the correct answer. Only tick one option unless otherwise instructed.

Examples of how to mark the questionnaire

Age [13] Years

	Yes	No
To answer "no"	[ ]	[✓]
To answer "yes"	[✓]	[ ]

Your Name: [ ]

School: [ ]

Today's Date: [ ] Day [ ] Month [ ] Year

Your Age: [ ] Years

Your Date of Birth: [ ] Day [ ] Month [ ] Year

(Tick all your answers for the rest of the questionnaire)

Are You: Male [ ] Female [ ]

To which ethnic group(s) do you belong? European/ Pakeha [ ] Maori [ ] Pacific Islander [ ] Other [ ]

Specify [ ]

19.3 Language codes:

Code	Language
001	Afrikaans
002	Albanian
003	Amharic
004	Arabic
005	Basque
006	Chinese
007	Dutch
008	English
009	Estonian
010	Filipino
011	Finnish
012	French
013	Georgian
014	German
015	Greek
016	Guarani
017	Gujarati
018	Hebrew
019	Hindi
020	Indonesian
021	Italian
022	Japanese
023	Korean
024	Latvian
025	Malay
026	Maltese
027	Malyalam
028	Marathi
029	Moroccan Arabic
030	Norwegian
031	Persian
032	Polish
033	Portuguese
034	Romanian
035	Russian
036	Spanish
037	Swedish
038	Tamil
039	Thai
040	Turkish
041	Ukrainian
042	Urdu
043	Xhosa

19.4 Guidelines for the 13/14 year age group survey

1. When a randomly selected list of schools has been generated for your centre (some centres will use all schools therefore a random list will not be necessary), a phone call to each school secretary to ask the Principal's name will mean that a personalised letter can be sent (example page 38). Include a sample of the questionnaire, information letter to parents/guardians, a copy of any translations and any other relevant information, for example a copy of the local ethics committee approval.

2. Keep a record of every contact that is made with the schools, the dates of phone calls, dates the letters are sent and names of all contact people especially the secretary as this may be the person you have most contact with.

3. Ring the school one week after the letter has been sent to speak to the Principal and discuss the process that would be undertaken for approval to be given. If necessary arrange a meeting to speak personally to the Principal and others (e.g. Board of Trustees, teachers).

4. When permission has been granted, arrange a time to visit to discuss the logistics of running the survey and identify who the school coordinator for the survey is to be. When the date of the survey has been agreed upon, arrange to take the parent information letter (example page 40) and any necessary translations of the letter to the school. Ask that these are distributed by the teacher, to the class (or age group) one week prior to the agreed date of the survey. In most centres, passive consent will be considered adequate by the local Ethics Committees, however this needs to be clarified by each individual centre. Request that a list of the students in the classes involved (or age group) is available on that day for your use and if possible, obtain date of birth, gender and ethnic origin on this list. As it is anticipated that some students will be absent on the first visit, arrange a date for a follow up visit.

5. If passive consent is approved by the local Ethics Committee, refusals will be accepted by:

   a) A phone call to the researcher (or appropriate person) by the Parent/Guardian;
   b) Sending the information letter back to the school (or researcher) with a written response and including the students name; or
   c) Verbal refusal from the student (as long as the excuse is plausible).

6. If written consent is required, this will be an appropriately worded section, attached to the information letter, asking the parent/guardian to return the slip to the school or another appropriate place. The class lists provided by the school should then be marked to identify the students who are not to participate with the rest of the class.

7. Conducting the survey.

   There are two possible methods of successfully conducting the survey.

   Option One: Numbering and naming the questionnaire prior to the survey date – this can only be done if the class lists are obtained prior to the survey. The surveys are then distributed to the students by name and class – any not given out are kept to be used on the second visit. The information printed onto a label that is fixed to the questionnaire prior to the survey may include Name; Sex and Date of Birth obtained from school lists.

Option Two: Handing out the blank surveys to the class (or age group) on the day for the students to complete. The fieldworker later marks them off against the lists provided by the school and creates a chart for those that did not complete the survey. This chart is then presented to each teacher on the second visit or posted prior to the second visit and the reason noted down. The students are then included in the follow-up visit.

Example:
Reasons for non participation

Student Name	Class Number	Absent	Not in age group	Refusal
Joe B	AR	✓		
Sam T	AR		✓ 12 years	
Andy G	BT	✓		
Mark S	GF		✓ 15 years	
Philip R	GF	✓		
Michael T	GF			✓ verbal from student

The advantage of using option Two is that the information given by the students can be checked against the information supplied by the school e.g. date of birth and age. Any wrong information given by the student or the school can then be checked.

8. The video questionnaire must always be shown after the written questionnaires and should be tested prior to the students being present to ensure that the sound and quality are of adequate quality to be heard and seen by all the students (video questionnaire Page 30).

9. Check that the written questionnaire intended for the 13/14 year olds is identified. For New Zealand, we have office use only boxes to code the age group, the year term used, how many surveys were issued to the student and location and language (example page 72–75).

10. Ensure that each student has a pen or pencil to write with (the survey is often done outside the home classroom).

11. A short explanation is beneficial before handing out the questionnaires. Students are more attentive if the researcher shows them the questionnaire and explains simultaneously. Instructions not to answer the video questionnaire until directed, not to discuss the questions (or answers) and to raise their hand if they have any queries are necessary. Instructions on how to alter an incorrect answer should also be given.

12. Survey forms are then given out either: by Name for Option One, or general issue to the class for Option Two.

13. Principles to follow regarding fielding questions from participants are attached (see standardised approach to fielding questions on page 78). It is important to answer questions individually and quietly so as not to influence the other students.

14. For option 2 checking the front page before students leave is advantageous and allows the student to make the corrections. However, this is not always possible. A check may be done later and the questionnaire reissued to the student on the second visit if practicable.

15. If questionnaires have not been completed in a comprehensible fashion, they could be returned to the original student for one further attempt (this may be logistically difficult).

16. Once the questionnaire is completed, the core questionnaire responses must not be changed by researchers/field workers under any circumstances. The demographic information on the front page may be corrected if errors are detected and the correct answer can be confirmed from school information. Any changes must be noted on a correction sheet (see example page 88).

17. Students must not be allowed to change their responses to the written questionnaire after viewing the video.

18. Confirm with the coordinating teacher the date of the return visit for absentees and, if yet to be made, organise the date, preferably within two weeks of the first visit.

19. If, on the second visit, the researcher surveys a class or classes that had been absent at camp or away entirely, they should be classified as first surveys and only the students who were absent from their class on the first visit, will be second surveys (if centres are collecting this information).

20. A letter of thanks from the researcher/field worker to the Principal and coordinating teacher is appropriate at this stage. Let them know that they will be notified of the results when they become available.

19.4.1 Standardised Approach for Fielding Questions

Some students will ask questions relating to their understanding of the questions or the response required during the survey conducted in secondary schools.

The teacher(s) should not be involved in explaining the study or the method of answering questions. This must be the responsibility of the ISAAC research field worker(s) who have been carefully briefed.

The principles to follow are:

1. Speak only to the individual who has the problem (identified by a raised hand). The first step is to read the written question out softly, exactly as it is written.

2. *If the student is still unable to answer the question,* the next step is to encourage them to think about the meaning.

3. *If the student is still unable to answer the question,* the next step is to give a little information without explaining the response required.

4. *If the student is still unable to answer the question,* the last step is to state that if the student really does not know how to respond, they should leave the question blank.

   If a student with learning difficulties has a helper who wishes to assist that child, the above guidelines should be followed.

Below are some examples for questions that commonly cause difficulties:

Question 1

Have you ever had wheezing or whistling in the chest at any time in the past?

Stage 1
Student response: ***"What is wheezing or whistling?"***

Researcher response to individual student only, say aloud but in a quiet voice:
"Have you ever had wheezing or whistling in the chest at any time in the past?" (i.e. read the question exactly as it is written).

Stage 2
Student response: ***"What is wheezing or whistling?"***

Researcher response to individual student only, say aloud but in a quiet voice:
"Words mean different things to different people. I want to know what you understand by this. Interpret it the best you can."

Stage 3
Student response: ***"I don't understand wheezing or whistling."***

Researcher response to individual student only, say aloud but in a quiet voice:
"Wheezing or whistling is related to your breathing. You would probably know if you have had it."

Stage 4
Student response: ***"I still don't understand this. I don't know if I have ever had it."***

Researcher response to individual student only, say aloud but in a quiet voice:
"If you really don't know then leave it blank."

Question 6

Have you ever had asthma?

Stage 1
Student response: ***"What is asthma?"***

Researcher response to individual student only, say aloud but in a quiet voice:
"Have you ever had asthma?" (i.e. read the question exactly as it is written).

Question 6 cont.

Stage 2
Student response: ***"What is asthma?"***

Researcher response to individual student only, say aloud but in a quiet voice:
"Words mean different things to different people. I want to know what you understand by this. Interpret it the best you can."

Stage 3
Student response: ***"I don't understand asthma."***

Researcher response to individual student only, say aloud but in a quiet voice:
"Asthma is related to your breathing. You would probably know if you have had it."

Stage 4
Student response: ***"I still don't understand this. I don't know if I have ever had it."***

Researcher response to individual student only, say aloud but in a quiet voice:
"If you really don't know then leave it blank."

Question 8

In the last 12 months have you had a dry cough, apart from a cough associated with a cold or chest infection?

Stage 1
Student response: ***"What is a dry cough?"***

Researcher response to individual student only, say aloud but in a quiet voice:
"In the last 12 months have you had a dry cough, apart from a cough associated with a cold or chest infection?" (i.e. read the question exactly as it is written).

Stage 2
Student response: ***"What is a dry cough?"***

Researcher response to individual student only, say aloud but in a quiet voice:
"Words mean different things to different people. I want to know what you understand by this. Interpret it the best you can."

Stage 3
Student response: ***"I don't understand a dry cough."***

Researcher response to individual student only, say aloud but in a quiet voice:
"It is not a wet one. There is no phlegm. It is just a dry cough. You would probably know if you have had it."

Stage 4
Student response: ***"I still don't understand this. I don't know if I have ever had it."***

Researcher response to individual student only, say aloud but in a quiet voice:
"If you really don't know then leave it blank."

Question 12

In which of the last 12 months did this nose problem occur?

Stage 1
Student response: ***"I can't remember."***

Researcher response to individual student only, say aloud but in a quiet voice:
"In which of the last 12 months did this nose problem occur?" (i.e. read the question exactly as it is written).

Stage 2
Student response: ***"I can't remember."***

Researcher response to individual student only, say aloud but in a quiet voice:
"Think hard about this, you may remember something."

Stage 3
Student response: ***"I still can't remember."***

Researcher response to individual student only, say aloud but in a quiet voice using local examples for each month:
"Try and remember – did you have it in January (e.g. Summer/Winter holiday)?
February (e.g. when school started at the beginning of the year)?
March (e.g. Easter)?
April?
May (e.g. May holidays)?
June?
July?
August (e.g. August holidays)?
September?
October?
November?
December (around Christmas time)?"

Stage 4
Student response: ***"I still can't remember when I have had it."***

Researcher response to individual student only, say aloud but in a quiet voice:
"If you really don't know then leave it blank."

Question 14

Have you ever had hayfever?

Stage 1
Student response: ***"What is hayfever?"***

Researcher response to individual student only, say aloud but in a quiet voice:
"Have you ever had hayfever?" (i.e. read the question exactly as it is written).

Stage 2
Student response: ***"What is hayfever?"***

Researcher response to individual student only, say aloud but in a quiet voice:
"Words mean different things to different people. I want to know what you understand by this. Interpret it the best you can."

Stage 3
Student response: ***"I don't understand hayfever."***

Researcher response to individual student only, say aloud but in a quiet voice:
"Hayfever affects your nose. You would probably know if you have had it."

Stage 4
Student response: ***"I still don't understand this. I don't know if I have ever had it."***

Researcher response to individual student only, say aloud but in a quiet voice:
"If you really don't know then leave it blank."

Question 20

Have you ever had eczema?

Stage 1
Student response: ***"What is eczema?"***

Researcher response to individual student only, say aloud but in a quiet voice:
"Have you ever had eczema? (i.e. read the question exactly as it is written).

Stage 2
Student response: ***"What is eczema?"***

Researcher response to individual student only, say aloud but in a quiet voice:
"Words mean different things to different people. I want to know what you understand by this. Interpret it the best you can."

Question 20 cont.

Stage 3
Student response: ***"I don't understand eczema."***

Researcher response to individual student only, say aloud but in a quiet voice:
"Eczema affects your skin. You would probably know if you have had it."

Stage 4
Student response: ***"I still don't understand this. I don't know if I have ever had it."***

Researcher response to individual student only, say aloud but in a quiet voice:
"If you really don't know then leave it blank."

19.4.2 Instructions for conducting the video questionnaire in schools

ISAAC research staff and field workers should not use the term "asthma" when testing in the school. The phrase "breathing" or "a survey about breathing, skin and nose problems" are acceptable terms to use prior to showing the video.

- Ensure video is working and the sound and picture quality is adequate if possible prior to the students being present. PLEASE VIEW THE VIDEO BEFORE YOU SHOW IT TO ANY GROUPS OF CHILDREN, SO THAT YOU ARE FAMILIAR WITH THE CONTENT AND LAYOUT.

- The showing of the video must **follow** the completion of the written core questions on wheezing rhinitis and eczema and not be shown before.

- Hand out the answer sheets, and ask the children to fill in their name, age, sex and date of birth before the video starts.

- Ask the students not to discuss with their friends or the person they are sitting next to, the answers they give.

- Advise students not to begin completing the video questions until you request them to.

- Play the video.

19.4.3 The video questionnaire (AVQ 3.0)

The video questionnaire consists of questions, relating to five video scenes of young people with breathing problems. The questions require yes/no answers.

The video questionnaire starts with an initial introductory section, which is read out while a map of the world is shown on the screen. The first video scene is introduced and then shown.

Following this video scene, the map of the world returns to the screen, and a three part question

relating to the scene just viewed, is read out. This sequence of scene introduction, followed by showing the scene, then followed by a three part question relating to the scene, is repeated for each of the five scenes.

The whole video takes 7 minutes to show.

- as the picture (a map of the world) comes on the screen, you will hear a tone. This is to indicate you start reading the instructions from * (refer page 31)

- each time you hear the tone, move on to the next item on the instructions, marked by *, and read it out

- you will note that some items are one sentence only, whereas others involve several sentences

- read all the instructions that are in capital (upper case) letters each time

- read the questions after the scenes slowly

- after the video has been shown, ask the students if any have seen the video before

- If any have, ask them to put a "V" on the top right hand side of the questionnaires on the front.

- when collecting the questionnaires, ensure demographic questions are complete

- remind coordinating teacher, that you will return to administer the questionnaire to those students not present on the day

See page 31 for the verbal instructions that are to be read out as the video is played to the 13/14 year old students.

19.5 Suggested guidelines for the 6/7 year age group survey

1. When a randomly selected list of schools has been generated for your centre (some centres will use all schools therefore a random list will not be necessary), a phone call to each school secretary to ask the Principal's name will mean that a personalised letter can be sent (example page 39). Include a sample of the questionnaire, information letter to parents/guardians, a copy of any translations and any other relevant information, for example a copy of the local ethical approval.

2. Keep a record of all contacts made with the schools, the dates of phone calls, dates the letters are sent and names of all contact people especially the secretary as this may be the person you have most contact with.

3. Ring the school one week after the letter has been sent to speak to the Principal and discuss the process that would be undertaken for approval to be given. If necessary arrange a meeting to speak personally to the Principal and others (e.g. Board of Trustees, teachers).

4. When permission has been granted, an appointment is made for the fieldworker to visit the school. Arrange for class lists to be available on the day complete with the child's name age, date of birth and ethnic origin, if possible. Like the 13/14 year age group, the questionnaires could be prenamed and ready for distribution by the teachers. However the cooperation of the teaching staff is essential to ensure that the children return the questionnaires, therefore, it may facilitate good will for the fieldworker to complete the naming of the questionnaires at the school, collate into classes and give to the teachers to hand out at the end of the day. The personal contact with the teachers cannot be underestimated and is the key to achieving a high participation rate.

5. Because the younger age group take the questionnaire home for parent/guardian completion, the following points can be of assistance to the fieldworker:

    a. Print an appropriate number of stickers that can be stuck on the bottom of the information letter e.g. '*Please return by Friday'* or one other day, giving them about a week to complete and return the questionnaire to school (the information letter is taken home with the questionnaire (example page 41).

    b. If a small 'prize' for the children is found, they are encouraged to get the questionnaire completed so they can return it and claim the 'prize'. In Auckland, we found a printing company who kindly agreed to donate a book sticker. The teacher gave each child a sticker when the questionnaire was returned and this method proved very successful.

    c. Most schools will have a stamp with the school name on it. Use this on every questionnaire and save time.

    The centre number and the school number can be entered later. Mistakes will not occur as long as the school name has been stamped on the questionnaire. However, some may prefer to enter all the numbers at the time of first issue.

Step by step procedure for the 6/7 year age group.

Step (i) Class lists obtained and each child given a number beside the name.

Step (ii) Child's name entered onto questionnaire.

Step (iii) Child's unique number, survey, term, centre and school number entered onto questionnaire (centre and school numbers can be entered later as long as Step iv is completed).

Step (iv) Name of school stamped onto questionnaire.

Step (v) Letter to parent with relevant translation enclosed **inside** questionnaire (sticker with date of return put on the bottom of the information letter).

Step (vi) Each survey folded, with a final check to ensure that it has been numbered, named and school name stamped.

Step (vii) Bundles for each classroom held with 2 rubber bands (one horizontal and one vertical), class room number written on the top questionnaire.

Step (viii) Appropriate numbers of 'prizes' to accompany each classrooms questionnaires.

Step (ix) Note attached to each bundle of questionnaires, thanking the teacher. For example:
"Would you please ask the children to return these surveys by …./…./2001. This information is on the letter for the parent enclosed in the questionnaire. Would you please give them a (?sticker ['prize']) when they return the survey.

6. Some schools require a small introduction of the project to the members of staff. This can often be done at a morning tea break when at the school numbering the questionnaires.

7. Discuss with the Secretary when to return to collect the questionnaires. The timing of this should be approximately one week following the "Please return by Friday" (or one other day) on the letter to the parent. A phone call before returning to the school is usually appreciated by the staff. Enquire how many surveys have been returned and then decide if it is worth postponing the visit

8. On return to the school, sort all surveys into number sequence and then mark off on the class list. For the numbers not marked off, reissue another questionnaires using the same process as above, but the Survey Number will now be **2** instead of **1**

9. For second issues, inclusion of a stamped self addressed envelope may increase the % of returns. Some parents may prefer this method of return. If funds permit this may be a better option for some centres with the first issue also. Some schools may prefer this as it would mean less involvement for the teachers.

10. In the case of surveys returned uncompleted, reissue the survey but put a **2** above the **1**.
Note: Reissue returned BLANK SURVEYS on the premise that it could have been left in the child's bag and returned to get the 'prize'. A POSITIVE NO from the parent/guardian on the questionnaire would stop a reissue. Because of privacy issues, some parents may not want the school to collect the completed questionnaire - we had a good response from the 2nd issue with the envelope provided.

Note on the class lists of the surveys not returned and those returned blank and keep a record of the reissue date.

11. It may be a good idea to leave a few spare stamped self addressed envelopes with the school secretary, and request that any late returned questionnaires to the school be posted back to the researcher/fieldworker.

12. No further contact with the school is required, however, a thank you letter would be appreciated. Advise them that they will be notified of the results when they become available.

13. Surveys collected are put into a locked filing cabinet. Any returned by post are checked off against the class list and put into the appropriate class by number sequence. At a less pressured time the surveys can be checked against the class lists for correct date of birth, age, and numbering.

14. Any corrections to demographic data must be recorded (example page 88) and identified by the numbers in the “office use only” boxes.

15. The questionnaire must not be altered under any circumstances.

19.6 Changes to the Demographic data

Example of how the 'office use only' boxes are used to record any corrections made to the Demographic data. This ensures that any changes made are legitimate and can be identified and checked if necessary.

Signature of Researcher _____ Question Reason for Change

Office use only

1	1	0	6	0	1	9	3	1	2	0	3	6	

Primary, centre 1, school 6, child 193, 1st survey, term 2, Spanish language

Age — Age given did not match the DOB given. Checked with School DOB correct therefore age changed by Researcher. DOB and age did not match

1	1	1	0	0	0	0	4	1	1		1	1	

DOB — DOB and age did not match up. Checked with School. Q Had wrong DOB, therefore DOB changed by researcher.

1	1	1	8	0	0	6		2	1			1	

Date — The Date given by parent had wrong year (1892 instead of 1992). Researcher changed to reflect the correct date.

A full page of these blank boxes can be generated (and then photocopied for multiple copies) and hand completed by the person checking the questionnaires. This enables an up to date record to be kept of any changes and these pages can them be examined if there is a query regarding the changes.

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