ISAAC Phase II Centre Report – 10-11 Year Age Group

Country Name:		Country Code:	
Centre Name:		Centre Code:	
Date of Ethics Commitee Approval:		Age Group:	
Date Report Completed:			
Principal Investigator:			
Report completed by:			
E-mail address of above person			

Name of Local Ethics Committee:

If your institution or country does not have a formal ethics committee, please state this clearly

Who provided funding for fieldwork and data entry?

1. STUDY POPULATION

1.1 How is your study population defined?

- ☐ Geographic area only
- ☐ Geographic area and specific school type(s)
- ☐ Geographic area and specific ethnic group(s)
- ☐ Geographic area and specific language(s)
- ☐ Other

1.2 If you answered "Other" for question 1.1, please describe how your study population is defined.

➡ **<u>To all:</u>**
Please send a detailed map showing the boundaries of the study area to the ISAAC II coordinating and data centre (I2CDC). A commercially available map with the ISAAC II boundaries clearly marked with a pen would be ideal.

1.3 Did you include different ethnic groups?

- ☐ Yes
- ☐ No

1.4 If yes, which ethnic groups and what percentages of each ethnic group were included? *(If you do not know the exact proportion, please give your best approximation!)*

Ethnic Group	exact %	approximate %

1.5 If you did include different ethnic groups, can you identify which children belong to which ethnic group in your sample?

☐ Yes

☐ No

1.6 If you have answered „Yes" to question 1.5., is the identification possible from any variable in the data you have sent to the I2CDC (e.g. from the child ID or school ID)?

☐ Yes

☐ No ⟶ If not, could you please provide such a variable to the I2CDC

If yes, please specify:

2. SCHOOLS

2.1 What kind of sample did you take?

- ☐ All schools in the study area (population)
- ☐ Random sample of schools
- ☐ Random sample stratified by school type (therefore the number of schools drawn for each school type reflects the proportion of pupils within the respective school type)
- ☐ Any other type of sample

2.2 If you answered "Any other type of sample" for question 2.1, please specify.

2.3 How many schools in total (for the selected age group) were there in your study area (population)? ☐

2.4 How many pupils in total (for the selected age group) were there in your study area (population)? *(If you do not know the exact number, please give your best approximation!)*

exact number ☐ best approximation ☐

2.5 Did you exclude any schools from sampling before approaching the schools?

- ☐ Yes
- ☐ No

2.6 If yes, please give the number of excluded schools and describe your reasons why these schools were excluded.

2.7 Did you exclude any schools from sampling after approaching the schools?

☐ Yes

☐ No

2.8 If yes, please give the number of excluded schools and describe your reasons why these schools were excluded.

2.9 How many schools did you approach? ☐

2.10 How many pupils (of your selected age group) were in the approached schools? *(If you do not know the exact number,please give your best approximation!)*

exact number ☐ best approximation ☐

2.11 How many of the approached schools participated? ☐

2.12 How many pupils (of your selected age group) were in the participating schools? *(If you do not know the exact number,please give your best approximation!)*

exact number ☐ best approximation ☐

2.13 How many pupils (of your selected age group) in the participating schools were selected for participation? ☐

2.14 How many of these pupils (of your selected age group) did actually participate? ☐

3. CLASSES AND CHILDREN

3.1. Did you select the children according to the ISAAC II standard protocol i.e. select the classes in which the majority of the children were aged 10 yrs 0 months to 10 yrs 11 months at the start of the fieldwork

☐ Yes

☐ No

3.2 If you have answered "No" to question 3.1 please describe how you selected the classes/ pupils within the schools?

3.3. Within each school, did you include all classes/ pupils which fulfilled the above criteria?

☐ Yes

☐ No

3.4. If you selected by class, did you include all children within each (selected) class, i.e. also those children outside of the ISAAC II standard age range (10 yrs 0 months to 10 yrs 11 months) ?

☐ Yes

☐ No

3.5. If you included children outside of the ISAAC II standard age range (10 yrs 0 months to 10 yrs 11 months), did you submit the data on these children to the I2CDC?

☐ Yes

☐ No

3.6. If you answered "No" to question 3.5., is this data available upon request by the I2CDC?

☐ Yes

☐ No

4. SAMPLING AND SUBSAMPLING

4.1 Further details on sampling

a) Please indicate in the tables whether you have used a full sample or a subsample for the respective modules. *(please tick the appropriate boxes in the table below. For module abbreviations see Coding Manual p.13 or Annex I of this questionnaire)*

Module	DC	WH	RH	EC	CP	WB	AM	RM
Full sample (Option A)								
Random subsample after stratification by wheeze in the past year (Option B)								
Other subsampling method								
Not collected								

Module	EM	RF	ED	SP	BR	IgE	DNA	Dust
Full sample (Option A)								
Random subsample after stratification by wheeze in the past year (Option B)								
Other subsampling method								
Not collected								

b) If you ticked "Other subsampling method" in the tables above, please describe the method(s) used for the respective modules.

c) Did the pool of children from which you have drawn the subsample of non-wheezers include the children that had missings in WH02 (wheeze in the past 12 months) because they were skipping question WH02 after having answered "No" to the filter question WH01 (wheeze ever).

☐ Yes

☐ No

4.2 Details on subsampling

Please answer this question only if you applied option B i.e. selecting a stratified subsample of at least 100 wheezers and 100 non-wheezers (see Phase II Modules p.7):

a) How many wheezers did you invite for participation? ☐

b) How many wheezers did actually participate? ☐

c) How many non-wheezers did you invite for participation? ☐

d) How many non-wheezers did actually participate? ☐

5. DETAILS ON PARTICIPATION RATES

5.1 Please indicate for each module the number of children selected to participate and the number of children that actually participated – ignore modules you have not conducted.

Module	DC	WH	RH	EC
number of children **selected** to participate				
number of children that **actually** participated				

Module	CP	WB	AM	RM
number of children **selected** to participate				
number of children that **actually** participated				

Module	EM	RF	ED	SP
number of children **selected** to participate				
Number of children that **actually** participated				

Module	BR	IgE	DNA	Dust
number of children **selected** to participate				
Number of children that **actually** participated				

5.2 Is there any information available about non-respondents?

☐ Yes

☐ No

If yes, please specify:

5.3 Did you have any difficulties getting the number of children that you needed for the required sample size?

☐ Yes

☐ No

5.4 If you answered "Yes" to question 5.3., please specify which difficulties you did encounter.

6. DATA ENTRY

6.1 How did you enter the data?

☐ Entering it directly into a table (e.g. in Excel,…)

☐ Using a data entry mask i.e. data are entered into a form and are transcribed to a table by the program (e.g. Epi Info or Access data entry mask,…)

☐ Using another method

6.2 If you have answered "using another method" to question 6.1 please describe the method you used.

6.3 Did you use:

a) ISAAC II coding standard (according to the ISAAC II Coding Manual) already for data entry?

☐ Yes

☐ No

b) Or did you recode the data to ISAAC II coding standard after data entry?

☐ Yes

☐ No

6.4 If you did recode:

a) Did you write a program for this (e.g. in SAS, SPSS, Excel-Macro)?

☐ Yes

☐ No

b) Did you use existing "find and replace" functions of an editor (e.g. Excel,...)?

☐ Yes

☐ No

c) Did you use any other method?

☐ Yes

☐ No

If yes, please describe:

6.5 Was the data double entered?

☐ Yes

☐ No

6.6 If yes:

a) Were the two data entries performed by different staff?

☐ Yes

☐ No

b) Did you compare the two data sets and check for any differences between them before sending the data to the I2CDC?

☐ Yes

☐ No

6.7 Have you checked the data for any data entry errors before sending it to the I2CDC?

☐ Yes

☐ No

6.8 If yes, please describe your method for checking for data entry errors.

6.9 Were any changes made to the demographic data after the questionnaires were completed?

The demographic data is the information concerning the sex, date of birth and date of interview for each child. You may have changed this data, if you noticed that the child or parent had written an incorrect value and the correct information was available from the school.

☐ Yes

☐ No

6.10 Were any changes made to any of the data other than correcting for data entry errors?

☐ Yes

☐ No ⟶ Please continue with question 6.13

6.11 If you have answered „Yes" to question 6.10., please indicate for which modules and variables you have made changes, and describe the changes made.

6.12 If you have answered „Yes" to question 6.10., please describe the reasons why you have changed the data.

6.13 Did you use any automatic coding with respect to filter questions <u>in the core questionnaire</u> (e.g. if WH01 = 2 then all values in WH02 are coded with 2 automatically)?

☐ Yes

☐ No

6.14 If you have answered yes to question 6.9, 6.10 or 6.13: have you kept a copy of the data without the changes?

☐ Yes

☐ No

7. TRANSLATION OF WRITTEN QUESTIONNAIRES

7.1 Did you use the English language questionnaire for data collection?

☐ Yes

☐ No

7.2 Did you use any translations of the English language questionnaire for data collection?

☐ Yes

☐ No

7.3 Was the translator familiar with asthma and allergy terminology?

☐ Yes

☐ No

7.4 Were the translated questionnaires translated back to English by an independent translator?

☐ Yes

☐ No

7.5 How many languages were used for your centre in this age group? ☐

7.6 Please name the languages and give the approximate proportions of questionnaires that were used in each language. *(If you do not know the exact proportion, please give your best approximation!)*

Language	exact %	approximate %

7.7 If you have used questionnaires in more than one language, can you identify which children used which language in your sample?

☐ Yes

☐ No

7.8 If you have answered „Yes" to question 7.7, is the identification possible from any variable in the dataset you have sent to the I2CDC (e.g. in the child ID or school ID)?

☐ Yes

☐ No

If yes, please specify:

8. CARRYING OUT THE MODULES

8.1 Did you use the ISAAC II questionnaires as self-administered questionnaire or as interview form? *(Please tick the appropriate boxes in the table below – ignore modules you have not conducted. For module abbreviations see Coding Manual p.13 or Annex I of this questionnaire)*

Module	DC	WH	RH	EC	CP	WB	AM	RM	EM	RF
self-administered questionnaire										
interview form										

8.2 When did you perform the fieldwork for the different modules? *(Please write the month and year of beginning and end of fieldwork into the tables below – ignore modules you have not conducted.)*

Modules	DC	WH	RH	EC
Begin				
End				

Modules	CP	WB	AM	RM
Begin				
End				

Modules	EM	RF	ED	SP
Begin				
End				

Modules	BR	IgE	DNA	Dust
Begin				
End				

8.3 Were your fieldworkers trained based on the ISAAC II study protocol? *(please tick the appropriate boxes for each module - ignore modules you have not conducted)*

	Skin examination	Skin prick test	Bronchial challenge	Blood sampling
Yes				
No				

8.4 If you answered „No" for any module of 8.3, please specify according to which protocol you did train your field workers.

8.5 Where were the examinations of the children carried out? *(please tick the appropriate boxes for each module - ignore modules you have not conducted)*

	Skin examination	Skin prick test	Bronchial challenge	Blood sampling
In the clinic				
In the field				

9. SKIN EXAMINATION

9.1 For the identification of flexural dermatitis, did field workers use: *(more than one answer possible)*

- ☐ the photographic protocol provided by Prof. Dr. Hywel Williams
- ☐ the practical manual "So how do I define atopic eczema?" provided by Prof. Dr. Hywel Williams
- ☐ other

9.2 If you answered "other" to question 9.1, please describe how field workers proceeded for the identification of flexural dermatitis.

9.3 Did you train your fieldworkers according to the practical manual "So how do I define atopic eczema?" provided by Prof. Dr. Hywel Williams

- ☐ Yes
- ☐ No

9.4 Did field workers perform the quality control tests that were included in the above mentioned manual?

- ☐ Yes
- ☐ No

9.5 Were the results of these quality control tests sent to Prof. Dr. Hywel Williams?

☐ Yes

☐ No

9.6 If not, how did you assure quality?

9.7 Did you modify the original ISAAC II protocol for Skin Examination (as specified in the ISAAC Phase II Modules, 1998) in any way?

☐ Yes

☐ No

9.8 If yes, please describe your modifications !

10. SKIN PRICK TEST FOR ATOPY

10.1 Did you use ALK lancets from ALK Denmark?

☐ Yes

☐ No

10.2 Did you use ALK allergen extracts from ALK Denmark?

☐ Yes

☐ No

10.3 Did you use any additional allergen extracts (i.e. other than *D. pteronyssinus, D. farinae, Alternaria tenuis,* cat, mixed grasses, mixed trees).

☐ Yes

☐ No ⟶ Please continue with question 10.8

10.4 If yes, please specify which extracts you used.

10.5 Which company did you purchase these additional extracts from?

10.6 Was the data on these additional extracts included in the data sent to the I2CDC?

☐ Yes

☐ No

10.7 If no, is it available on request?

☐ Yes

☐ No

10.8 At what time(s) of the day did you perform the skin prick tests?

(Please indicate a.m. and p.m., respectively)

_____

_____

_____

_____

_____

10.9 Did you test the precision/reproducibility for each field worker?

☐ Yes

☐ No

10.10 If yes, <u>when</u> did you test the precision/reproducibility?

	Yes	No
Begin of field work	☐	☐
Middle of field work	☐	☐
End of field work	☐	☐

10.11 If yes, <u>how</u> did you test the precision/reproducibility?

☐ As indicated in the manual of the ISAAC II Modules, 1998

☐ Other

10.12 If you answered "other" to question 10.11, please describe how you have tested precision/reproducibility.

10.13 Did you modify the original ISAAC II protocol for the Skin Prick Test (as specified in the ISAAC Phase II Modules, 1998) in any way?

☐ Yes

☐ No

10.14 If yes, please specify!

11. BRONCHIAL RESPONSIVENESS TO HYPERTONIC SALINE

11.1 Did you perform bronchial challenge to determine bronchial responsiveness?

☐ Yes

☐ No

If no, please specify why not?

➡ If you did not perform any kind of bronchial challenge, please continue with question 12.

11.2 Did you perform bronchial challenge with hypertonic saline?

☐ Yes

☐ No ⟶ Please continue with question 11.7

➡ The following questions (11.3 to 11.6) relate only to hypertonic saline challenge.

11.3 Inclusion criteria

a) Which formula did you use to calculate the predicted FEV_1 for a child?

☐ Automatic calculation by spirometer

☐ Other calculation

If other, please specify here.

b) Did you apply any other inclusion or exclusion criteria than those mentioned in the ISAAC Phase II Modules, 1998?

☐ Yes

☐ No

If yes, please specify.

11.4 Did you modify the original ISAAC II protocol for Bronchial Responsiveness to Hypertonic Saline (as specified in the ISAAC Phase II Modules, 1998) in any way?

☐ Yes

☐ No

If yes, please specify.

11.5 Technical information

a) Which type of nebuliser did you use?

☐ Ultrasound

☐ Other (please specify) _____

Technical information *(11.5 continued):*

b) Which brand of ultrasound nebuliser did you use?

☐ Timeter Compuneb 500

☐ Devilbis Ultraneb 2000

☐ Other (please specify) _____

c) Which type/brand of tubing did you use?

☐ Bennetts Cat No TV 2723

☐ DeVilbiss No 8885, Silicon

☐ Other (please specify) _____

d) Was the used tubing as suggested app. 60-70cm of length?

☐ Yes

☐ No

If no, please specify.

e) Which type/brand of two-way valve did you use?

☐ Hans Rudolph two-way non-rebreathing valve 2700

☐ Laerdal valve No 560 200 / 850 500

☐ Other (please specify) _____

f) Which type/brand of spirometer did you use?

☐ MasterScope (Jäger)

☐ Other (please specify) _____

Technical information *(11.5 continued):*

g) Did this spirometer comply with the "Recommendations of the Am. Thoracic Soc. Stat. on Standardization of Spirometry"?

☐ Yes

☐ No

h) Which type/brand of balance did you use?

☐ Sartorius Basic 2100

☐ Mettler 3000

☐ Other (please specify) _____

i) Was this balance a precision balance?

☐ Yes

☐ No

j) Did you use saline solution with a concentration of 4.5%?

☐ Yes

☐ No

If no, what concentration did you use?

11.6 Some questions concerning the procedure of bronchial challenge:

a) Did you determine the baseline value of FEV_1 by obtaining measurements within 5% variability?

☐ Yes

☐ No

If no, please specify how you did determine it.

b) Did you perform the bronchial challenge according to the ISAAC Phase II Modules?

☐ Yes

☐ No

If no, please specify why not and how you performed the challenge.

c) Did you determine the amount of aerosol delivered by weighing the tube before and after challenge?

☐ Yes

☐ No

If no, how did you determine the inhaled amount of saline?

11.7 Did you perform bronchial challenge with another method (like exercise or metacholine challenge)?

☐ Yes

☐ No

If yes, please specify briefly and send us your challenge protocol.

12. LAST BUT NOT LEAST:

We would welcome further comments regarding any difficulties that you encountered during the conduct of the study.

Thank you very much for completing this report !

Your ISAAC Phase II Coordinating Team
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For further questions and/or comments please contact:

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ANNEX I

Module abbreviations:

Demographic characteristics	DC
Questionnaire on wheezing	WH
Questionnaire on rhinitis	RH
Questionnaire on eczema	EC
Cough and phlegm	CP
Wheeze and breathlessness	WB
Asthma management	AM
Rhinitis management	RM
Eczema management	EM
Risk factor Questionnaire	RF
Examination for flexural dermatitis	ED
Skin prick tests for atopy	SP
Bronchial responsiveness to hypertonic saline	BR