Assessment of Asthma Management in Children Over 6 Years of Age and Their Caregivers: Implications for the Implementation of the SMART Strategy in Pediatrics

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Protocol Code: IIBSP-EMA-2025-05

Short Title: Asthma Management in Children

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ASTHMA STUDY INFORMATION AND CONSENT FORM (CHILDREN UNDER 10 YEARS)

Study Title: Assessment of Asthma Management in Children Over 6 Years of Age and Their Caregivers: Implications for the Implementation of the SMART Strategy in Pediatrics
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Sponsor: Institut de Recerca de l'Hospital de la Santa Creu i Sant Pau – IIB Sant Pau
Principal Investigator: Victòria Morón Faura, Pediatrics Department, Pediatric Pulmonology and Allergy Day Hospital, vmoron@santpau.cat
Center: Hospital de la Santa Creu i Sant Pau

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1. Introduction

You are receiving this information as a parent or guardian of a child invited to participate in a research study. This study has been approved by the appropriate Clinical Research Ethics Committee. You will receive sufficient information to decide whether to allow your child to participate. Please read this sheet carefully and ask any questions you may have. You may also consult anyone you consider appropriate.

2. Voluntary Participation

Participation is voluntary. You may choose not to participate or withdraw consent at any time without affecting your child's medical care or your relationship with their physician.

3. Study Overview

Your child is invited to participate in a program to evaluate whether a brief nursing intervention can improve asthma management and inhaler use. The study lasts approximately six months and includes two visits:

Visit 1: Screening & Baseline

- Verify eligibility for you and your child.
- Collect basic data (age, sex, education level).
- Perform routine lung function tests.
- Child demonstrates inhaler use.
- Both parent/guardian and child complete brief questionnaires.

Nurse Education Session

- Practical instruction with illustrated materials on correct inhaler use.
- Explanation of treatment indications.
- Guidance on recognizing worsening asthma and actions to take.

Visit 2: 6-Month Follow-Up

- Repeat activities from Visit 1 to assess progress.

No additional invasive procedures are required. Usual treatment with your child's pulmonologist will not change. Approximately 428 children and their caregivers will participate.

4. Expectations

You and your child are expected to: - Attend study visits. - Assist your child with questionnaires. - Allow the nurse to observe inhaler use.

No blood or additional samples beyond routine respiratory tests will be collected.

5. Benefits and Risks

Direct benefits may not occur, but data collected may improve future asthma care strategies. No additional risks are anticipated beyond routine clinical care.

6. Confidentiality

Data will be handled according to EU Regulation 2016/679 and Spanish Organic Law 3/2018. Data will be pseudonymized, with only the principal investigator able to link it to your child. Access is restricted to authorized personnel and relevant regulatory bodies. No international transfers will occur. You may exercise your data rights through the principal investigator or the Data Protection Officer at dpd@santpau.cat.

7. Compensation

Participation will not incur any costs or compensation.

8. Additional Information

Data may be used in future related studies. For questions or more information, contact:
Mrs. Victòria Morón Faura
Pneumoallergy Day Hospital, Floor E, Room B, HSCSP
Tel: 93 291 9000 ext. 8079

By signing the attached consent form, you agree to the study conditions.

INFORMATION FOR CHILDREN AGED 6–10 YEARS

- You are invited to participate to see if a short session with a nurse can help you understand your asthma and use your inhaler correctly.
- You will attend two visits over six months with your parent/guardian.
- Visit 1: Check eligibility, show inhaler technique, perform familiar breathing tests, answer simple questions.
- Nurse session: Learn correct inhaler use, understand your device, recognize worsening asthma.
- Visit 2: Repeat activities to see what you have learned.
- Participation is voluntary; you can stop at any time by telling your parents or nurse.

CHILD INFORMED CONSENT (UNDER 10 YEARS)

I, (Full Name) _____,

- Have read the information sheet provided
- Have been able to ask questions
- Have received sufficient information
- Have discussed it with: _____ (Investigator's Name)

I understand that my participation is voluntary and that I can withdraw:

1. At any time
2. Without providing a reason
3. Without affecting my medical care

I freely consent to participate in this study and allow access and use of my data as described in the information sheet. I will receive a signed and dated copy of this information and consent form.

Child Signature: _____ **Date:** _____
Investigator Signature: _____ **Date:** _____

This form will be signed in duplicate, with one copy for the investigator and one for the child.

PARENT/GUARDIAN INFORMED CONSENT

I, (Parent/Guardian Name) _____, as (Relationship) _____ of (Child Name) _____,

- Have read the information sheet provided
- Have been able to ask questions
- Have received sufficient information
- Have discussed it with _____

I understand that my child's participation is voluntary and may withdraw:

1. At any time
2. Without providing a reason
3. Without affecting their medical care

I freely consent to _____ (Child's Name) participating in the study. I will receive a signed and dated copy of this information and consent form.

I authorize the use of collected information in future related studies: ☐ YES ☐ NO

If only one parent consents, they must declare:

- I confirm that the other parent does not oppose my child's participation in the study.

Name: _____ **Date:** _____ **Signature:** _____
If the signatory is the sole legal guardian:
Name: _____ **Date:** _____ **Signature:** _____