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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PARTICIPANT INFORMATION SHEET AND INFORMED CONSENT (AGES 11-17)

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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Department: Pediatrics Center: Hospital de la Santa Creu i Sant Pau

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PARTICIPANT INFORMATION SHEET

You are invited to participate in this study. This sheet provides information to help you decide whether to participate. Participation is voluntary, and you can withdraw at any time without affecting your medical care.

Purpose of the Study: The study aims to determine if a brief educational intervention and nurse demonstration can help you manage your asthma better, use your inhaler correctly, and recognize when it needs to be used.

Eligibility: Children aged 6–17 years with a diagnosis of asthma, who have used an inhaler for at least six months, and who attend the Pediatric Pulmonology Clinic at our hospital.

Study Duration and Visits: - **Visit 1 (Screening & Baseline):** Eligibility check, basic data collection (age, sex, school), routine breathing tests, inhaler demonstration, simple questionnaires. - **Nurse Education Session:** Practical guidance with illustrated materials on inhaler use, treatment indications, and recognizing worsening asthma. - **Visit 2 (6-Month Follow-Up):** Repeat of previous activities to assess changes.

No additional invasive or painful tests are required beyond standard care.

Data Protection: Personal data will be pseudonymized using a code. Only the principal investigator can link the code to your identity. No identifiable information will be disclosed.

Additional Information: Data may be used in future related research with your consent. For questions, contact: Mrs. Victòria Morón Faura Pneumoallergy Day Hospital, Floor E, Room B, HSCSP Tel.: 93 291 9000 ext. 8079

PARTICIPANT INFORMED CONSENT

I, (Full Name) _____, have read the information sheet, had the opportunity to ask questions, and received sufficient information about the study. I understand participation is voluntary and may withdraw at any time without affecting my care.

I consent to participate and allow access to my data as described in the information sheet. I authorize the use of collected data in future related studies: ☐ YES ☐ NO

Participant Signature: _____ Date: _____ Investigator Signature: _____ Date: _____

PARENT/GUARDIAN INFORMED CONSENT

I, (Parent/Guardian Name) _____, as (Relationship) _____ of (Child Name) _____, have read the information sheet, had the opportunity to ask questions, and received sufficient information.

I understand my child's participation is voluntary and may withdraw at any time without affecting care. I freely consent to my child participating in this study.

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

Parent/Guardian Signature: _____ Date: _____ If only one parent consents, confirmation that the other parent does not oppose: Name: _____ Date: _____ Signature: _____

A copy of this form will be kept by both the participant and the investigator.