INTRO: Welcome to FluSNIFF! We are testing a nasal flu vaccine that is already approved for children aged two and older. Now we want to see if it is safe in younger children.

What is this clinical trial about?

We are testing the safety of a nasal flu vaccine spray in children aged 12–23 months. The spray (Fluenz) is already approved in children aged 2 years and older and given each winter. Depending on the results of this clinical trial, the NHS may offer it to 1-2 year old children in the future.

Who can join?

Any child aged 12 months up to one day before their second birthday and in generally good health. We will ask about allergies, medicines, and any medical history to make sure your child can safely take part.

What will happen?

Visit 1 (in GP clinic, ~30 min)

- Re-confirm consent and check health.
- A computer will randomly choose whether your child gets the flu spray or a harmless spray (placebo) at this visit.
- This is called a blinded trial. This means you will not be told whether your child received the flu vaccine or the placebo (salt water) at each visit. This helps make sure the study results are reliable. The study team at your GP practice will know which spray your child received. You can find out which spray your child received after the study ends if you wish.

Visit 2 (in GP clinic, 28 days later, ~30 min)

- Ask about any symptoms since Visit 1.
- Your child gets the other spray (flu vaccine if they had placebo first, or vice versa).

Please note: participation in this trial requires you to bring your child to your GP practice in person for the first and second appointments. Please ensure you are able to do this before you consent to take part.

Follow-up (Day 56, by phone or online)

- Ask about any health problems in the 28 days since Visit 2.

You'll be asked to complete a short electronic diary (under 5 minutes) at 7 and 14 days after each visit, to report any urgent or emergency NHS care your child needed. If your child is admitted to hospital before the final visit, please inform the study team by email or phone.

Possible benefits & risks

- Benefit: Your child will receive the nasal flu vaccine for free, which may protect against severe flu.

- Common mild side-effects: Runny nose, cough, fever usually last 1–2 days.

- The vaccine has been shown to be highly effective in this age group in previous clinical trials. The vaccine will not protect against other viral infections which are not caused by the influenza virus.

- Rare risks: Allergic reaction (rash, swelling, difficulty breathing). The study team is trained and prepared to treat this unlikely event immediately.

- We will watch closely for any wheezing and record any doctor visits for breathing problems.

Your rights

- Your choice: Taking part is voluntary. You can withdraw at any time—no reason needed—and your usual medical care will not be affected.

- If you withdraw: No new data will be collected, but data and samples already gathered may still be used unless you ask us to remove them (where allowed).

Data sharing & privacy

- Your child's routine health records (GP notes, NHS Digital data, hospital records) will be shared with uMed on behalf of the study team.

- We will keep your child's data secure and coded so they cannot be identified in any reports.

- Anonymous data may be used for future flu research without asking you again.

How we use your information

- What personal data we collect

We will collect personal data including your name, contact details, your child's date of birth, medical history, NHS number, and data about their study participation.

- How we use your data

We use this information to check eligibility, conduct the clinical trial, ensure participant safety, and meet regulatory requirements.

- Legal basis for using your data

The legal basis is that this clinical trial is carried out in the public interest. This is in accordance with the UK General Data Protection Regulation (GDPR).

- Who we share your data with

Identifiable data is only shared with the study team, sponsor, and regulators (where required). De-identified data may be used in future research without additional consent. Your data will not be shared outside the UK.

- How long we keep your data

We will keep your study data for a maximum of 25 years. The study data will then be fully anonymised and securely archived or destroyed.

What are your choices about how your information is used?

You can leave the trial at any time without giving a reason. We will keep any data we've already collected unless you ask us not to.

If you leave the trial, we'd like to continue collecting health information from your GP. You can ask us to stop this at any time.

You can also ask to access, correct, or delete your data. We'll explain if there are cases where we legally need to keep using it for research.

If you take part, your data may be used (anonymously) in future flu research, unless you say no.

Where can you find out more about how your child's information is used?

You can find out more about how we use your child's information at:

- Our leaflet at www.hra.nhs.uk/patientdataandresearch
- By asking one of the research team
- By sending an email to flusniff@umed.io
- By ringing uMed on 08000554877

Once enrolled in the trial:

- By sending an email to dataprotection@uhs.nhs.uk
- By ringing 023 8120 4743

Who runs the clinical trial?

Sponsor: University Hospital Southampton NHS Foundation Trust

Research sites: GP practices and hospitals around England

Research facilitator: uMed works on behalf of the Sponsor and Research sites and identifies eligible children, sends invitations to participate, manages consent, collects information from parents, extracts study-related data, and sends it to the research team—following UK data-protection rules.

uMed's role in contacting families and supporting recruitment for this trial has been reviewed and approved by the Health Research Authority's Confidentiality Advisory Group (CAG)

(CAG reference: 26/CAG/0037 dated 15 June 2026)

This short survey will ask about your child's health to check if they can join.

(Please answer each question about your child. Questions are simple "Yes" or "No.")

1. **Age**

    - Please confirm your child was born between <insert dates>

      ⬜ Yes ⬜ No

      <If no - end journey & show 'Thank you! Your child is not currently eligible to join this trial. You may be invited to join again at a later date. >

2. **Health**

    - Is your child generally **well and healthy**
      ⬜ Yes ⬜ No

      <If no - end journey & show Thank you! Your child is not currently eligible to join this trial. You may be invited to join again at a later date

3. **Previous Wheeze**
    - Has your child been diagnosed with bronchiolitis, asthma, or viral wheeze by a doctor? ⬜ Yes ⬜ No

4. **Previous Eczema**
    - Has your child been diagnosed with eczema by a doctor? ⬜ Yes ⬜ No

5. **Previous Health**
    - Has your child been diagnosed with any other medical conditions by a doctor? ⬜ Yes ⬜ No

        i. You answered yes, do any of these conditions currently require frequent hospital/specialist input or have recently required hospital admission? ⬜ Yes ⬜ No

      <If Yes - end journey & show "Thank you! Your child is not currently eligible to join this study. You may be invited to join again at a later date" >

6. **Previous Flu Vaccines**

    - Has your child ever had a **seasonal flu jab (injection)**?
      ⬜ Yes ⬜ No

<If Yes - end journey & show "Thank you! Your child is not currently eligible to join this study. You may be invited to join again at a later date" >

- Does your child receive invitations to have the **seasonal flu jab (injection)**?

  ⬜ Yes ⬜ No

  <If Yes - end journey & show "Thank you! Your child is not currently eligible to join this study. You may be invited to join again at a later date" >

7. **Other Research Vaccines**

   - In the last **30 days**, has your child taken part in another **vaccine research study,** or are they planned to take part in another vaccine study **before the end of this autumn?**
     ⬜ Yes ⬜ No

     <If Yes - end journey & show Thank you! Your child is not currently eligible to join this study. You may be invited to join again at a later date>

8. **Immune System**

   - Does anyone in your home have a **very weak immune system** (for example, someone on strong medicines for cancer or organ transplant)?
     ⬜ Yes ⬜ No

     <If Yes - end journey & show Thank you! Your child is not currently eligible to join this study. You may be invited to join again at a later date>

9. **Blood Products**

   - In the last **3 months**, has your child received a blood transfusion or other **blood products** or immunoglobulin (antibody) treatments?
     ⬜ Yes ⬜ No

     <If Yes - end journey & show 'Thank you! Your child is not currently eligible to join this study. You may be invited to join again at a later date>

10. **Allergies**

- Does your child have a serious allergy to **gelatin, or gentamicin**?
  ⬜ Yes ⬜ No

  <If Yes - end journey & show Thank you! Your child is not currently eligible to join this study. You may be invited to join again at a later date>

11. **Allergy History**

- Has your child ever had a **severe allergic reaction** (anaphylaxis)?
  ⬜ Yes ⬜ No

  <If Yes - end journey & show 'Thank you! Your child is not currently eligible to join this study. You may be invited to join again at a later date>

12. **Other Serious Illness**

- Does your child have cancer, severe heart or lung disease, or a serious neurological illness (like Guillain-Barré)?
  ⬜ Yes ⬜ No

  <If Yes - end journey & show 'Thank you! Your child is not currently eligible to join this study. You may be invited to join again at a later date">

13. **Planned Surgery**

- Is your child booked for any **planned surgery** during the next 2-3 months?
  ⬜ Yes ⬜ No

  <If Yes - end journey & show Thank you! Your child is not currently eligible to join this study. You may be invited to join again at a later date>

14. Medication

- Is your child currently taking aspirin or any medicines containing salicylates?

  ⬜ Yes ⬜ No

<If Yes - end journey & show Thank you! Your child is not currently eligible to join this study. You may be invited to join again at a later date>

15. Participation in other clinical trials

- Has your child been involved in any other research studies where they received a medicine as part of the study within the past 12 weeks?
  ⬜ Yes ⬜ No

  <If Yes - end journey & show Thank you! Your child is not currently eligible to join this study. You may be invited to join again at a later date>

16. **Language & Consent**

    - Can you read English and use SMS or email so we can send you study information and online forms?
      ⬜ Yes ⬜ No

      <If no - end journey & show 'Thank you! Your child is not currently eligible to join this study. You may be invited to join again at a later date. >

Great news! Based on your answers, your child can join the FluSniff study. Please continue to consent.

If you'd prefer to speak to someone first, don't worry, you'll be shown how to get in touch with the FluSNIFF team at the end of this section.

Comprehension & Confirmation Page

Once the PIS is read:

- Present a checklist of 4 "I understand…" / "I agree…" statements.

No.	Statement
1	**Understanding & Consent** ● I have read the information and understood it. ● I have asked any questions I needed and am happy to proceed. ● I agree that by clicking "I consent" I give legal permission, just like a paper signature.

2	**Voluntary Participation & Withdrawal** ● I understand that taking part is my choice. ● I can withdraw my child at any time, for any reason, without affecting our medical care. ● If I withdraw, no new data will be collected, but already-collected data may still be used unless I ask for its removal.
3	**Data Sharing & Privacy** ● I agree that my child's GP can share routine health records (GP notes, NHS Digital data, hospital records) with uMed for this study. ● I agree to enter health updates sent by text or email. ● I consent to study staff or uMed checking my child's hospital records if needed to confirm safety events. ● I agree that anonymous (de-identified) data may be used in future flu research without asking me again.
4	**Treatment Allocation** ● I understand that a computer will choose by chance which spray my child gets first (flu spray or placebo spray), and that they will get the other spray later.

- Each statement has a checkbox (must all be ✓ before the "I Consent" button unlocks).
- Include a "Back" link to revisit PIS.

Electronic Signature Capture

- When "I Consent" is clicked, prompt for:
    - **Parent/Guardian identity verification**
    - **Signature action** (e.g. "Type your full name" + checkbox acknowledging e-signature equivalence).
- Record: user ID, date/time stamp, IP address, doc version.

- Generates a HTML email that **can't be altered** after it's sent, **the exact version** of the text they saw is clear, and **all signature metadata** (user ID, date/time stamp, IP) is permanently linked to that document.

Confirmation page - "Congratulations you have completed the form. You will now be contacted to arrange an appointment. Study visits will usually take place at your child's GP clinic. In a few cases, they may instead be held at a nearby hospital. You will be informed ahead of time if this applies to you".