

Beaumont Hospital, Dublin

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**Information Leaflet**

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| **Study title: Toxicosurveillance of Exposure to Laundry Detergent Capsules – A 24 Month Prospective Study** |

**Principal investigator’s name: Dr. Edel Duggan**

**Principal investigator’s title: Director, National Poisons Information Centre**

**Telephone number of principal investigator: 01 809 2772**

**Co-investigator’s name: Feargal O’ Connor**

**Co-investigator’s title: Specialist in Poison Information**

**Data Controller’s Identity: Beaumont Hospital Board**

**Data Controller’s Contact Details: 01 809 2873**

**routineaccess@beaumont.ie**

**Data Protection Officer’s Identity: Mark Graham**

**Data Protection Officer’s Contact Details: 01 809 2162**

 **dpo@beaumont.ie**

You are being invited to take part in a study to be carried out at Beaumont Hospital by the National Poisons Information Centre.

Before you decide whether or not you wish to take part, you should consider the following information carefully and, if you wish, discuss it with your family, friends or GP (doctor). Take time to ask questions – don’t feel rushed and don’t feel under pressure to make a quick decision.

You should clearly understand the risks and benefits of taking part in this study so that you can make a decision that is right for you. This process is known as ‘Informed Consent’.

You don't have to take part in this study. If you decide not to take part it won’t affect you/your child’s future medical care.

You can change your mind about taking part in the study any time you like.  Even if the study has started, you can still opt out. You don't have to give us a reason.  If you do opt out, rest assured it won't affect the quality of treatment you get in the future.

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| **Why is this study being done?** |

Laundry detergent capsules are common household products. Following reports of accidental exposures to these products, this study aims to understand how these accidents occur and which types of packaging the products were in. The results will be used to help prevent similar accidents occurring in the future.

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| **Who is organising this study?** |

The National Poisons Information Centre (NPIC) is organising the study. The study has been approved by the Beaumont Hospital Ethics medical Research Committee.

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| **Why am I being asked to take part?** |

You are being asked to take part in the study because your child has been exposed to a laundry detergent capsule and advice on this exposure was sought from the NPIC.

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| **How will the study be carried out?** |

The study will be carried out in the NPIC in 2024 and 2025 and will involve about 100 people. A questionnaire will be used to collect data by telephone interview with parents of children (aged 3 years and under) exposed to a laundry capsule. It should take 5-10 minutes to complete the questionnaire.

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| **What will happen to me if I agree to take part?** |

If you consent to take part, you will be invited to answer a telephone questionnaire which should take 5-10 minutes of your time. You will be asked questions about the product involved, the circumstances of the accident, if symptoms developed, if your child needed to be seen by a doctor and what the outcome was. You can refuse to take part in the study at any time.

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| **What are the benefits?** |

There are no benefits for you or your child if you agree to take part in this study. However, we hope this study will help us to understand the circumstances surrounding accidental exposures to laundry detergent capsules and help prevent accidents occurring in the future.

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| **What are the risks?** |

There are no risks for you or your child if you agree to take part in this study.

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| **What if something goes wrong when I’m taking part in this study?** |

The staff of the NPIC answer calls every day concerning children and adults who have been accidently exposed to household products. If you get upset during the telephone questionnaire, the person calling you will be sympathetic and assure you that you can decide not to continue, if you do not wish to. If you have any complaints about the study, you can talk to the Director of the NPIC on (01) 809 2772 or the Patient Representative in Beaumont Hospital on (01) 809 3234.

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| **Will it cost me anything to take part?** |

There are no costs involved.

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| **Is the study confidential?** |

You/your child’s personal details and the information about the exposure to the laundry detergent capsules will be ‘coded’. This means that the researchers will remove all personal details from the information they collect and thus ensure that your/your child’s information will remain private and confidential.

**Data Protection**

1. Your privacy is important to us. We take many steps to make sure that we protect your confidentiality and keep your data safe. Your name and telephone number will be noted and stored securely in the NPIC office so that we can contact you in a couple of days time to complete the study questionnaire.

2. We will rely on Article 6.1(e) ‘public interest’ and Art 9.2 (j) ‘scientific research purposes’ of the General Data Protection Regulations to process your personal data. We are processing your data for scientific research purposes and for the legitimate interests of the NPIC and in the public interest, to help prevent accidental exposure to laundry detergent capsules occurring in the future. We will also ask for your explicit consent to use your data for this study.

3. Only the staff of the NPIC (8 people) will have access to your personal data.

4. Your data will be stored in the NPIC office until the study results have been published and will then be disposed of securely.

5. There is very little risk of your personal data being accessed by a third party. Your name and telephone number will be used for the sole purpose of contacting you to complete the study questionnaire. Your personal data will not be transferred outside the NPIC.

6. You have the right to withdraw consent at any time. You can do this during the follow up phone call with the NPIC staff member or by contacting the NPIC at any time on 01-8092166.

7. You have the right to lodge a complaint to the Data Protection Commissioner if you feel your data is being or has been misused.

8. You have the right to have to access your personal data and receive a copy of it.

9. You have the right to object to any further processing of the information we hold about you.

10. You have the right to have inaccurate information about you corrected or deleted.

11. You have the right to have your personal data deleted, unless your request would make it impossible or make it very difficult to conduct the research, for example, you wanted to delete your data at the end of a research project just before it is due to be published.

12. You have a right to move your data from one controller to another in a readable format.

13. No automated processing (eg. profiling) will be performed at any time on your data.

14. However, you are entitled to the right to object to any automated processing of your data, if you so wish.

15. Your data will only be used for the purpose of this study.

16. Your personal data will not be shared with any third parties.

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| **Where can I get further information?** |

If you have any further questions about the study or if you want to opt out of the study, you can rest assured it won't affect the quality of treatment you get in the future.

If you need any further information now or at any time in the future, please telephone Feargal or Patricia in the NPIC on (01) 809 2166 (7 days 8am-10pm).