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PARTICIPANT INFORMATION LETTER

TITLE: Understanding the risk factors contributing to outcomes of older perioperative patients in Ireland: The Irish Perioperative OutcomeS (IPOS) Study

INVESTIGATOR: <Insert the site PI details>

SPONSOR: Health Service Executive (HSE)

Background

As medical care and surgical methods improve, more older adults with other health conditions can have major surgeries. Currently, there is limited detailed information about the factors that are important to achieve best results for patients in Ireland. Since Ireland's population is aging and more people have multiple health problems, the number of high-risk surgical patients is expected to rise. Without good data on what causes poor surgical outcomes here, it is hard to plan healthcare services or improve care effectively.

Why we're doing this Study

We are doing a large study across hospitals in Ireland to better understand factors that are important to achieve best outcomes in older people that present for surgery requiring a hospital stay in Ireland. We want to find out how often problems occur, what makes them more likely, and what happens to patients afterward. We intend to use this information to improve care for future patients.

To do this, we will look at your hospital chart and collect some basic medical information, such as your age, sex, medical history, the type of surgery you had, and whether you had any problems after surgery.

Risks and Benefits

There are no direct benefits to you from being part of this study. But what we learn could help improve care for future patients.

The only possible risk is to the privacy of your medical information. However, we will keep all your information safe and private. Your name will not be used in any reports, and only a special study number will be used to identify your data. None of your personal details will be shared outside <Insert your hospital name>.

For the purposes of this study, pseudonymised data (data in which personal identifiers have been replaced with a study code) will be transferred to and processed by Galway University Hospital. Only authorized members of the research team at GUH will have access to this data.

Some people involved in the study — like the sponsor or hospital ethics team — may look at your medical records to make sure the study is being done properly. They will also keep your information private.

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What will happen to your data?

Your data will be assigned a unique study number and securely transferred to the Health Services Executive at Galway University Hospitals, which is the data controller for this study. They will not have access to any of your personal information, as all data transferred will be coded to protect your privacy.

Your Rights regarding this Study

You have important rights in regard to your information that was collected in this study:

1. You have the right to access your personal information that was collected during the study
2. You have the right to withdraw from the study and have the data collected erased
3. You can restrict or object to the processing of your personal data

If you wish to exercise any of these rights or just would like to find out further information regarding the study, and your rights as participants within the study, please contact <insert your PI or relevant contact details>

Your Choice to Take Part

If you don't want us to use your medical information in this study, please complete the 'Withdrawal form' we have provided. Please send this form to <insert your relevant contact details> within six months after you leave the hospital as after this point the study database will be locked for analysis with your coded information.
Choosing not to take part will not affect your care in any way.

Would you like to know about the results of this study?

If you would like us to send you a summary of the key findings of this study when it is published, please contact <insert your relevant contact details> within two weeks after you leave the hospital, and we will arrange for a copy of the major findings to be sent to you.

Questions?

If you have questions or concerns about the study or your rights as a participant, you can contact:

- **PI contact details**
- **Data Protection:** Racheal Batten; Racheal.Batten@hse.ie
- **Clinical Research Ethics Committee** at <contact details>

The ethics committee is an independent group that checks to make sure studies are done fairly and safely. Anything you talk to them about will be kept private.