**The self-expressed quality of life of Irish adults with early diagnosed phenylketonuria on long term dietary therapy.**

**Information Letter**

Below are some frequently asked questions which I hope will help people to gain a better understanding for the reasoning behind our research.

**What is this study about?**

To date, extensive research has highlighted the metabolic and scientific effects felt by people with PKU. These studies have flagged a correlation between PKU and how it effects people’s mood and wellbeing, however the how and why have yet to be discussed. The intention of this study is to look at the lived experience of people with PKU in hope of improving services and patient centered care.

**Why is this study important?**

This study is important because it will provide us with data that will help to develop recommendations for creating awareness and informing future decision making. We are also hoping to develop recommendations and guidelines that may help to improve services and to develop person centred treatment options.

**What will be required of me if I agree to participate?**

Should any members choose to participate in our study they will be asked to sit in an informal interview. Within the interview we will discuss the condition and how it has affected their lives, in both negative and positive ways. We will discuss the impact of the diet and any feeling or restrictions associated with it and anything else they may wish to discuss. I want people to express their own experience of living with PKU. There is a slight possibility that travel may be required, if so there is funding available.

**What are the benefits (direct/indirect) of participation?**

We are hopeful that this study will contribute towards raising awareness and informing future decision making. This study will also give people an opportunity to tell their story in their own words, highlighting what is important to them in regards to treatment and management of the condition.

**What are the risks of participation?**

At present there are limited risks associated with this research study. It is important to note that should you find the interview upsetting at any point it can be stopped and there is supports available through the PKU Association of Ireland. All participants will be given sufficient information before commencement of participation so that they can make an informed decision. There will be consent forms that each participant must sign to show that they are fully consenting to partake in the study. They will also have an opportunity at this time to ask any questions they may have.

**How will my identity be protected?**

All identities will be protected and full anonymity will be given to all participants, unless they choose to waive their right to anonymity. No names or factors that may identify people will be used within the study or in any future publications.

**Can I change my mind/withdraw at any time?**

Participants have the right to withdraw from the study at any point without fear of repercussion.

**How will my data be stored and for how long?**

All data will be stored securely in accordance with current data protection regulations. Only members of the research team will have access to this data. In accordance with current guidelines under the Irish University Association (2014), all data must be retained for a period of 5 years following the completion of research for the purpose of research verification. Following this period, all data will be destroyed accordingly.

**What will happen to the results? Will the research be published?**

The results of this study will be used to help in the development of recommendations and guidelines that may help to improve services and to develop person centered treatment options. In time the results of this study may be published but the identity of participants will continue to be protected.

**Who do I contact if I have further queries about this study?**

Anyone who wishes to participate or wants to know more information can do so by contacting me directly at [mary.ellen.oshea@research.ittralee.ie](mailto:mary.ellen.oshea@research.ittralee.ie)

**Who do I contact if I have a complaint/concerns about this study?**

If you have any complaints or concerns about this study and you wish to communicate with someone outside of the research team, you may do so by contacting the Chair, Institute Research Ethics Committee, Institute of Technology, Tralee.