CONSENT FORM

Title: Epidemiology, clinical profile, and outcomes of prolactinomas requiring high dose cabergoline treatment: the RESISTANT PROLACTINOMA study

Investigators: ENEA (European Neuroendocrine Association) members and Local Site ……

This consent form may contain words that you may not understand. Please ask the study doctor or the study staff to explain any word or information that you do not clearly understand. You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

Introduction: A rate as high as 15% of patients with prolactinomas do not respond to standard doses of dopamine agonists (DA) resulting in a failure to achieve a normal prolactin level on maximally tolerated doses of a dopamine agonist and a failure to achieve a 50% reduction in tumour size.

The purpose of this research study is to investigate the clinical and biochemical features, morphological characteristics, diagnostic approaches, treatment regimens and options as well as outcomes of patients taking a high dose cabergoline (≥ 3mg/week).

Confidentiality of Records: Information of this study will be given to the members of ENEA and RESISTANT PROLACTINOMA study group who will have the role of Principal Investigators. Medical records will not identify you and the consent form signed by you may be looked at and copied for research or regulatory purposes by the members of the Local Investigators:

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The results of this research study may be presented at meetings or in publications. The information obtained in this study may be published but your identity will not be revealed.

Voluntary Participation/Withdrawal: your participation in this study is voluntary. You may decide to not participate in this study. Your decision will not change your future medical care at this site. The study doctor or an ENEA representative may also decide to withdraw you from the study without your permission.

Questions: The study doctor is willing to answer any questions that you may have. You may ask questions concerning the study. If you have any questions, contact the study doctor: ……...

Do not sign this consent form un1ess you have had a chance to ask questions and have received satisfactory answers to al1 of your questions.

Consent: I have read this consent form. I understand the information about this study. All my questions about the study and my participation in it have been answered. I freely consent to participate in this research study.

1 understand that I wil1 receive a signed and dated Copy of this Consent form.

I authorize the release of my medical record for research or regulatory purposes as mentioned above.

Centre Number: Study Number: Patient Identification Number for this trial:

Please mark each box to indicate agreement or leave blank to indicate refusal. You may indicate agreement to some boxes and refusal to some other boxes.

1.	I confirm that I have read and understand the information sheet for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
2.	I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.	
3.	I understand that relevant sections of any of my medical notes and data collected during the study may be looked at by responsible individuals from regulatory authorities, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.	
4.	**If the study finds a change in management regarding my neoplasm, I wish to be informed of this through my hospital doctor and to discuss further therapeutic options.**	
5.	**Apart from the situation in section (4), I understand that the results of the research will not be made available to anyone, including me, on an individual basis; I also understand that the research will not directly benefit my health.**	
6.	I agree to take part in the above study.	

_____ _____ _____

Patient's Name Date Signature

Patient's Date of birth_____

Patient's Contact telephone, email and address_____

_____ _____ _____

Name of Person taking consent Date Signature