

**CAPS Registry Study Proposal**

**TITLE: <PROPOSAL EXAMPLE TITLE>**

**PROPOSING CENTER: <NAME OF CENTER>**

**PRINCIPAL INVESTIGATOR: <NAME OF PI>  
  
CONTACT INFORMATION: <E-MAIL ADDRESS>  
 <TELEPHONE NUMBER>**

**DATE: <DATE OF SUBMISSION>**

Please use the following sections to describe your study proposal concisely, e.g. in 2 pages.

**Background**

<Provide an introduction and rationale for this study proposal. Briefly explain the problem and provide convincing arguments that there is currently not sufficient knowledge available. State which new information this study may add to what is already known>

**Study hypothesis**

<Please state your hypothesis. Include the primary objective and, if applicable, also include the secondary objective(s)>

**Study population**

<Please clearly define the research population by outlining the inclusion and exclusion criteria, e.g. based on type of mutation, familial risk, age criteria, follow-up duration, used surveillance modalities, surveillance outcome etc.>

<State the minimal number of subjects required to provide a reliable answer to the primary objective. Clearly explain which method was used to calculate the size of the study population and why this method was chosen. If the sample size was determined on some other basis, please make this clear and justified>

**Research methods**

*Primary, secondary and tertiary study parameter(s)/endpoint(s)*  
<Please describe the main study parameter/endpoint and, if applicable, the secondary parameter(s)/endpoint(s). Specify which outcome variables from the registry are required to reach these parameters/endpoints>  
  
*Other parameters/endpoints*  
<Additionally, describe which other study parameters will be necessary for the analysis of the main study parameter(s). For example, which baseline values or parameters which might intervene with the main study parameter (confounders, e.g. body weight, smoking, etcetera) are required>  
  
*Statistical analysis*  
<For each of the parameters/endpoints mentioned above, describe in general terms how the data (categorical and/or continuous variables) will be presented (quantitative and/or qualitative), and how derived parameters will be calculated (if applicable). Explain how missing data will be handled. Specify which statistical analysis will be used and which subjects are to be included in the analyses (e.g. intention-to-treat analysis or per-protocol analysis). From the explanation it should be clear how the different objectives of the study will be answered>