

CONCEPT - INVESTIGATOR INITIATED STUDY (IIS)

Principal Investigator Full contact details and credentials	
Date of request:	

An Investigator Initiated Study (IIS) is a study involving human research developed and sponsored by an independent external entity, who initiates, manages and funds the IIS and assumes the legal and regulatory responsibility for the conduct and management of the study. An IIS is a study conducted without the participation of Aimmune/NHS for which the IIS sponsor requests from Aimmune/NHS in an unsolicited way to provide either funding, Aimmune/NHS products or both.

Please complete the form as applicable to your project.

Title	
Rationale and Background	
Study Objectives	Primary Objective: Secondary Objectives:
Study Design	
Number of Sites	
Number of Patients	
Study Population	
Study treatment	
Variables / Data collection	
Potential Risks / Limitations	
Costs	