



Project Title/Name:

Ancillary Study Principal Investigator:

Co-P.I.s:

Email address of P.I.:

Phone Number of P.I.

Date:

To be completed by PREDICT-HD Executive Science Committee during Project Approval Process

Portfolio:

PREDICT-HD

Section:

Project Number:

Brief Project Background & Description: *(What will this project do?) (255 characters):*

Objectives: *(Problem or Opportunity Statement / Background of Project Need)*

Statistical Analysis Plan: *(Provide brief description of statistical analysis plan and justification for number of PREDICT-HD subjects required for ancillary study)*



Study Variables needed to complete Project (e.g., CAG repeat length, age, education, digit symbol, motor total)

List Variables required

Preliminary Timeline: (Enter any applicable milestone or deliverable dates)

Milestone or Deliverable	Target Completion Date
(Ex. PIF finalized and approved)	
(Ex. IRB approval)	
(Ex. Data collected and Analyzed)	

Roles and Responsibilities: (Enter the estimated resources needed to initiate the project)

Role and Responsibilities of Ancillary Study PI:

Roles and Responsibilities of PREDICT-HD IT infrastructure (briefly describe services required by ancillary study):

Participant/Site Requirements:

Are participants required? Yes No If yes, how many? Gene Positive Males _____ CAP Score(s) _____
 Gene Positive Females _____ CAP Score(s) _____
 Control Males _____ CAP Score(s) _____
 Control Females _____ CAP Score(s) _____

Specific Requirements of Participants: (list specific requirements needed from participants and what participants will do including the number of collection time points)

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Are sites required? Yes No If yes, how many? _____

Is IRB approval needed? Yes No

Specific requirements of sites: *(list specific requirement necessary of sites along with roles and responsibilities)*

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Endorsement *(to be completed by PREDICT-HD Scientific Executive Committee):*

Endorsed Not Endorsed Deferred until _____

Comments (Enter endorsement mechanism and any other comments)

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