Key: Delegation of Tasks for Clinical Research

This document defines the standard research tasks delegated to each role within the DF/HCC. Individuals are delegated the authority to perform the tasks appropriate for their role, as indicated below, unless otherwise noted on a protocol-specific delegation of authority log. Please note: this key is not all-inclusive; roles not captured here should be listed on the protocol-specific delegation of authority log.

Research Tasks	Physician	Physician Assistant (PA) / Nurse Practitioner (NP)	Research Nurse (RN)	Pharmacist	Coordinator [1]
GENERAL ACTIVITIES					
Assessment of inclusion/exclusion criteria	yes	Initial documentation: Requires evidence of confirmation by MD, before subject registration	Initial documentation; Requires evidence of confirmation by MD, before subject registration	no	no
Informed consent/assent	yes	Only when approved by the IRB	Only when approved by the IRB	no	Only when approved by the IRB
Vital signs	yes	yes	yes	no	As certified by institution
Physical exams	yes	yes	no	no	no
Medical history	yes	yes	Intake only; Medically focused evaluations done by MD/PA/NP	no	no
Orders for test article	yes	Initial assignment of research plan for first cycle must performed by physician investigator. All future treatments for that research plan can be written and signed by PA or NP if allowed per institutional policy.	no	no	no
Administration of test article	yes	yes	yes	no	no
DLT determination	yes	yes	Initial assessment; Requires evidence of confirmation by MD	no	no
Dose modification (including reductions, holds or restarts)	yes	yes	Initial assessment; Requires evidence of confirmation by MD	no	no

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ADVERSE EVENTS					
Intake/documentation of symptoms	yes	yes	yes	no	no
Assessment of grade using CTCAE; Assessment of clinical significance; Assessment of relationship to test article (i.e., attribution/causality)	yes	yes	Initial determination; Requires evidence of confirmation by MD, NP or PA	no	no
Transcription of grades from CTCAE for abnormal laboratory results	yes	yes	yes	no	yes
Assessment of expectedness	yes	yes	Initial determination; Requires evidence of confirmation by MD, NP or PA	no	Identification based on Current Version of Investigator Drug Brochure; Requires evidence of confirmation by MD, NP, or PA
SAE determination (i.e., event meets criteria for expedited reporting)	yes	yes	yes	no	If pre-specified in protocol; Otherwise requires evidence of confirmation by MD
Report to sponsor as SAE	yes	yes	yes	no	yes
Review of IND safety report from external sponsors	Yes, only when listed as a subinvestigator on the FDA Form 1572	Yes, only when listed as a subinvestigator on the FDA Form 1572	Yes, only when listed as a subinvestigator on the FDA Form 1572	No	Only initial triage and reviewing for expectedness in the Investigator Drug Brochure; requires confirmation by PI or sub-investigator
Final Determination of IND safety report requiring reporting to the IRB (DF/HCC subsite PIs should communicate with the Core Site. Only Core Site should make a single report to the IRB.)	Principal Investigator only	No	No	No	No

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DRUG/DEVICE					
Documentation of accountability and adherence by review of subject diary and count of test article returned by subject	yes	yes	yes	Only count of patient returns	Pill count and diary reconciliation only
Drug/device receipt from the sponsor, storage, dispensation, destruction, unused returns to the sponsor, and related documentation[2]	no	no	no	yes	no
SOURCE DOCUMENTS					
Writing in subject's medical record or research chart	yes	yes	yes	Pharmacy records only	Research chart only, unless granted institutional access to document in the medical record
STUDY PROCEDURES					
Subject Registration, IWRS Updates, and/or Randomization (*if other than sponsor or ODQ)*	yes	yes	yes	no	In collaboration with MD/PA/NP/Research Nurse
Lab sample processing, shipping or receiving	yes	yes	yes	no	yes
Evaluation of response results; Assessment of primary study endpoints	yes	Requires evidence of review with MD directly, by phone or email prior to research-related decisions	no	no	no
REGULATORY DOCUMENTS					
Maintain regulatory binder or essential documents	yes	yes	yes	no	yes
CASE REPORT FORMS (CRFs)					
Data transfer from source documents to CRF	yes	yes	yes	no	yes
Sign completed CRF	yes	no	no	no	no
Data query resolution	yes	yes	yes	no	yes
COMMUNICATIONS					

Research Tasks	Physician	Physician Assistant (PA) / Nurse Practitioner (NP)	Research Nurse (RN)	Pharmacist	Coordinator [1]
Communications and/or submissions to sponsors, IRB or federal authorities, and DF/HCC	yes	yes	yes	yes	yes

1 - Includes study coordinators, regulatory coordinators, and other non-medically licensed research personnel
2 – If not managed by pharmacy, responsible party should be listed on the protocol-specific delegation log