Dana-Farber/Harvard Cancer Center

Note-To-File

Date: June 21, 2021

RE: DF/HCC Policy Exemptions related to COVID-19 Pandemic

This note to file serves to extend the following temporary policy exemptions that initially took effect March 23, 2020 until at least September 30, 2021.

RCO-203 Regulatory Documentation Section 5.2.4

Individuals providing clinical coverage as a result of mandatory staffing restrictions are not required to be listed on the delegation of authority log. Appropriately trained and delegated research staff must remain accessible remotely and continue to ensure appropriate oversight of research activities. Communication between the covering staff and research team will be appropriately documented and maintained in the research subject file.

REGIST-100 Eligibility Checklists Section 5.3.2

Screening staff may confirm subject eligibility via email if they are unable to sign the checklist prior to registration. The email confirmation will be filed with the eligibility checklist in the research chart.

REGIST-100 Eligibility Checklists Section 5.3.4

Enrollment monitors may verify subject eligibility via email if they are unable to sign the checklist prior to registration. The email confirmation will be filed with the eligibility checklist in the research chart.

Sincerely,

Drew Memmott	Electronically signed by: Drew Memmott Reason: fm an approver Date: Jun 21, 2021 13:44 EDT	Jun 21, 2021	
Signature		Date	
Drew Memmott			
DF/HCC Associate Dire	ctor of Administration		
Jeffrey Meyerhardt	Electronically signed by: Jeffrey Meyerhard Resson: I'm an approver Date: June 7, 2021 15:14 EDT	Jun 21, 2021	
Signature		Date	
Jeff Meverhardt MD			

DF/HCC Medical Director for Clinical Trials Operations