

Dana-Farber/Harvard Cancer Center

Note-To-File

Date: December 12, 2020

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 June 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: I'm an approver
Date: Dec 12, 2020 10:22 EST

Dec 12, 2020

Signature

Date

Drew Memmott
DF/HCC Associate Director of Administration

Jeffrey Meyerhardt

Electronically signed by: Jeffrey Meyerhardt
Reason: I'm an approver
Date: Dec 12, 2020 10:40 EST

Dec 12, 2020

Signature

Date

Jeff Meyerhardt, MD
DF/HCC Medical Director for Clinical Trials Operations