

Dana-Farber/Harvard Cancer Center

Note-To-File

Date: March 23, 2020

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

This note to file serves to document the following temporary policy exemptions for all DF/HCC human subject research to take effect immediately and ending April 30, 2020.

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
Drew Memmott (Mar 23, 2020)

Signature

Drew Memmott

DF/HCC Associate Director of Administration

Mar 23, 2020

Date

Jeffrey Meyerhardt
Jeffrey Meyerhardt (Mar 23, 2020)

Signature

Jeff Meyerhardt, MD

DF/HCC Medical Director for Clinical Trials Operations

Mar 23, 2020

Date