Exhibit C: COVID-19 Immunization of Research Monitors

1) **Research Monitor Defined.** The term “research monitor” shall encompass any sponsor’s employees or agents, who provide research services related to a contract or agreement with UNC Health or its affiliates. The term “research monitor” does not include UNC Health employees or students in health education programs affiliated with UNC Health entities.

2) **Vaccine Requirement.** Any research monitor who visits or works at a UNC Health location or facility must receive a complete COVID-19 vaccine (i.e., obtain both doses if receiving a two-dose vaccine).

Monitors subject to the mandatory vaccine requirement include:

a) Monitors for sponsors with existing UNC Health (or affiliate) research contracts that explicitly require site based monitoring or other scheduled research activities; and

b) Monitors for sponsors with existing UNC Health (or affiliate) contracts that are silent as to immunization requirements where those monitors work or visit on site at UNC Health locations or facilities.

3) **Notice and Compliance.** Monitors will receive notification of the requirement to comply with the vaccine requirement as follows:

a) Monitors will receive a pre-visit notice of the COVID-19 vaccine requirement which will be sent by their UNC Health research contact by email.

b) The notice will contain a hyperlink to access an online form which must be completed prior to scheduling a site visit. The notice will contain:

   i) Attestation of compliance with the COVID-19 Immunization requirement for UNC Health. Research monitors must attest to being fully vaccinated prior to scheduling a visit to any UNC Health facility.

   ii) Confidentiality Statement (included for efficiency in executing all research monitoring requirements electronically)

   c) Monitors must be fully vaccinated at least two weeks (14 days) prior to visiting any UNC Health facility.

   d) UNC Health will not attempt separate verification of each monitor’s compliance with the vaccine requirement, but will reserve the right to request and audit records from the employer.

   e) The COVID-19 vaccination is mandatory for research monitors visiting UNC Health facilities. Use of a mask is not an acceptable alternative to receiving the COVID-19 vaccine.

   f) Alternatives: Research monitors who are not vaccinated or who have been exempted from vaccination by their employer may send a delegate/substitute, or they may conduct the visit remotely with assistance from the site-based study team.

      i) Research monitors should reschedule their visits to UNC Health facilities if they have symptoms of an infectious disease or exposure to communicable diseases per UNC Health policy.

      ii) Research monitors with signs or symptoms of an infectious disease or exposure to communicable diseases should be cleared by their occupational health department or local physician before visiting or working at UNC Health facilities.