



THE UNIVERSITY
of NORTH CAROLINA
at CHAPEL HILL

OFFICE OF THE VICE CHANCELLOR FOR RESEARCH

312 SOUTH BUILDING
CAMPUS BOX 4000
CHAPEL HILL, NC 27599-4000

T 919-962-1319
F 919-962-1476

October 11, 2017

RE: 21 CFR Part 11 Compliance Certification

To: Whom It May Concern

This letter is to confirm that The University of North Carolina at Chapel Hill's (UNC-CH) electronic Institutional Review Board information system (IRBIS), meet the system, process and policy requirements of 21 CFR part 11. Additionally, UNC-CH self-certifies that all electronic signatures executed in IRBIS are legally binding and the equivalent of hand-written signatures. Security rights to access IRBIS are given only to those individuals approved to review applications. Sharing of passwords is prohibited. Changes to records in IRBIS are recorded in a secure, electronically, generated audit trail.

Sincerely,

A handwritten signature in black ink, appearing to read "Andy Johns", with a long horizontal flourish extending to the right.

Andy Johns
Sr. Associate Vice Chancellor for Research