Title: Transition from Provisional to Full Certification Approval Email Template

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General Description & Purpose: This is the email template used by the MCC Study Team to transition a Provisionally Certified Site to full Certification Approval for a given study.

Instructions: The MCC Study Team will retrieve the site's Provisional Certification Approval email and use it as the starting place for the Transition from Provisional to Full Certification Approval email. <u>After replying to all and ensuring that the original Provisional Certification Approval Email is retained in the body of the message</u>, the Study Team will use the template below in the new section of the reply-all email. This step ensures that all certification-approval-related documentation is preserved in a single, continuous email chain.

The sections of the template noted in red should be updated to reflect the name of the institution, individual, or study, as necessary.

Please note: You should <u>erase and replace the subject line</u> to reflect the text below.

Subject Line: Full Clinical Site Certification Approval Granted for the <<Study Acronym/Short Name>>

New Section of Email (above previous Provisional Certification Approval):

Dear <<PI Name>>,

Congratulations! Your site has fully satisfied all requirements for Full Clinical Site Certification for the <<Study Acronym/Short Name>> Study. We appreciate that you participated in the Provisional Certification quality assurance process and hope that you, too, feel even more prepared and confident as you re-initiate screening and enrollment activities.

The members of your study team who were provisionally certified on <<date of Provisional Certification>> are hereby granted full certification approval.

Please Note: If new individuals join your study team, they must be certified by the MCC prior to initiating study activities.
- You should notify the MCC of any new study team members ASAP. Make sure to submit the required certification materials for those individuals along with your notice.
- After verifying all required documentation, the MCC will then *Reply All* to this approval message (transitioning your site from Provisional to Full Certification) and will include a new table (like

the one below), this time listing the newly certified individuals. The certification approval date for those new study team members will be the date that the *Reply All* message is sent.

- This process will be repeated any time there are new study team members to certify; each time the most recently sent certification-approval-related message will be the starting point. This will allow for a complete history of all certification approval activity to be maintained in one email chain.

Please file a copy of this email approval notice in your <<Study Acronym/Short Name>> Regulatory Binder.

Please let us know if you have any questions as you re-initiate study procedures

We thank you again for your contributions to this important study!

<<MCC Study Team Member Name>>

<< MCC Study Team Member Standard Signature Block>>