Guideline For Electronic Signatures in the Conduct of Human Subject Research During COVID-19 Pandemic

PURPOSE

The purpose of this document is to establish a standard method for applying electronic signatures in the conduct of human subject research at the University of Miami (UM) during the COVID-19 pandemic, as many researchers are working remotely and obtaining wet signatures may not be feasible.

FDA-regulated studies conducted under an Investigational New Drug (IND) or Investigational Device Exemption (IDE) application require that, in the absence of wet signatures, electronic signatures be obtained using a 21 CFR Part 11 (Part 11) compliant system; however, in the absence of a Part 11 compliant system and in the current circumstances where wet signatures cannot be obtained, the process described in this document is to be followed.

SCOPE

This electronic signature process only applies for a limited time, during the COVID-19 pandemic, where researchers and research team members are working remotely. It applies to any instance where a wet signature on paper would ordinarily be obtained by a research team member, with exceptions listed below.

The process described in this document should be followed when applying electronic signatures in a clinical trial being conducted under an IND or IDE.

Exceptions:
- This guideline does <u>not</u> apply to the informed consent process.   As per the HSRO's SOP HRP-093, Investigators must obtain IRB approval to document consent in an electronic format.
- This process is <u>not</u> intended to obtain electronic signatures from non-researchers such as research participants.

It is <u>recommended</u> that these guidelines also be followed for non-FDA regulated research.

DEFINITIONS

21 CFR Part 11	FDA regulation governing electronic records and signatures
FDA	Food and Drug Administration
HSRO	Human Subjects Research Office
IDE	Investigational Device Exemption
IND	Investigational New Drug application
Research team member	Personnel involved in the conduct of clinical trials, such as Principal Investigators, Sub-Investigators, Research Nurses, Study Coordinators
SOP	Standard Operating Procedure
UM	University of Miami

GUIDELINE

1) Researchers who need to apply an electronic signature should use **Adobe Acrobat Self Sign.** This is the method recommended by FDA when submitting electronic documents to them such as Form FDA 1571.

   Adobe Acrobat Self Sign requires the user to create a password and when the electronic signature is applied to a document, the following appears:

   - Printed name of Signer
   - Date and time of signature

2) Adobe Acrobat Self Sign is available free of charge to UM employees.
3) You will need to create a **Self Signed Digital ID**. To do this, follow the steps outlined below.
4) Save a copy of the signed documents in Box, OneDrive, or other approved UM document repository.

Signing Documents with an Adobe Self-Signed Digital ID

1. TO DOWNLOAD AND INSTALL ADOBE ACROBAT:

If you do not already have Adobe Acrobat installed on your computer or you need to update it, the application is free to all UM faculty, staff and students.

1. Go to https://www.it.miami.edu/a-z-listing/adobe-creative-cloud/index.html
2. Click on the login link and log in with your Cane ID username and password.
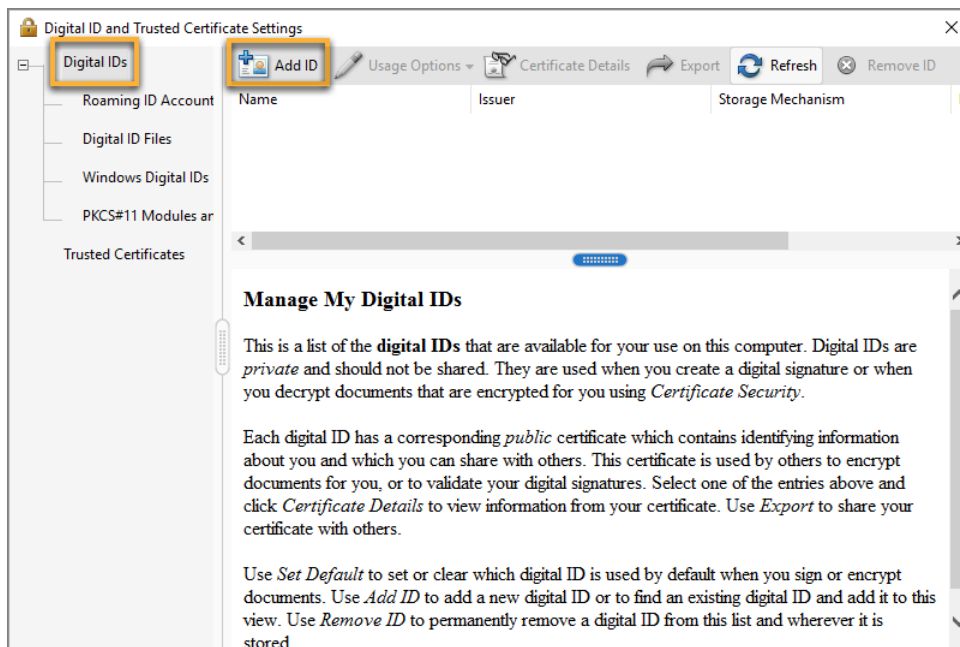
3. Follow the prompts to install Acrobat.

2. CREATE YOUR SELF-SIGNED DIGITAL ID:

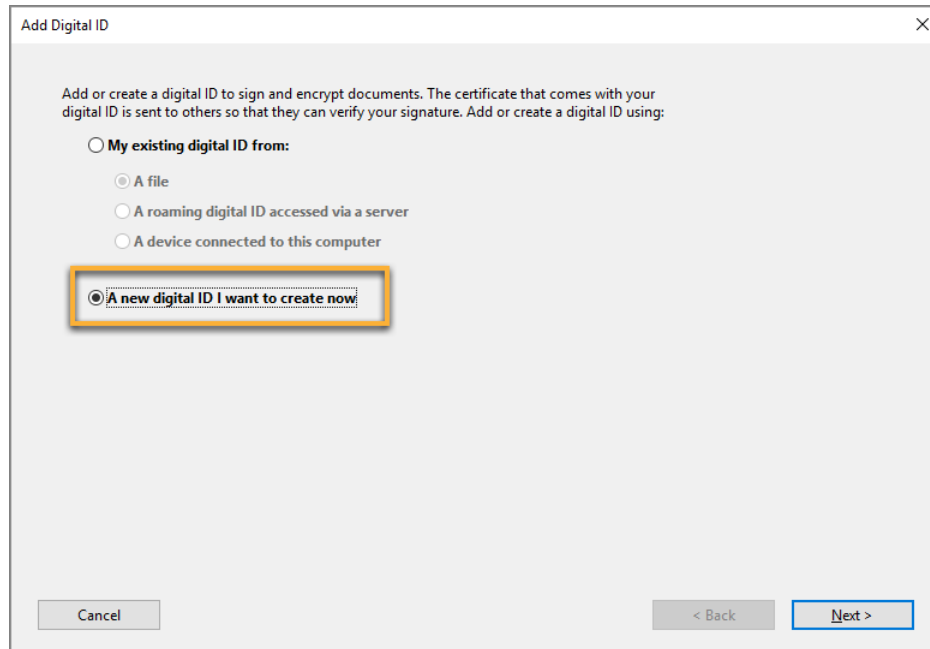Follow these steps to set up your self-signed digital ID. This only needs to be done once.

1. In Acrobat, click the **Edit** menu and choose **Preferences** > **Signatures**.
2. On the right, click **More** for **Identities & Trusted Certificates**.

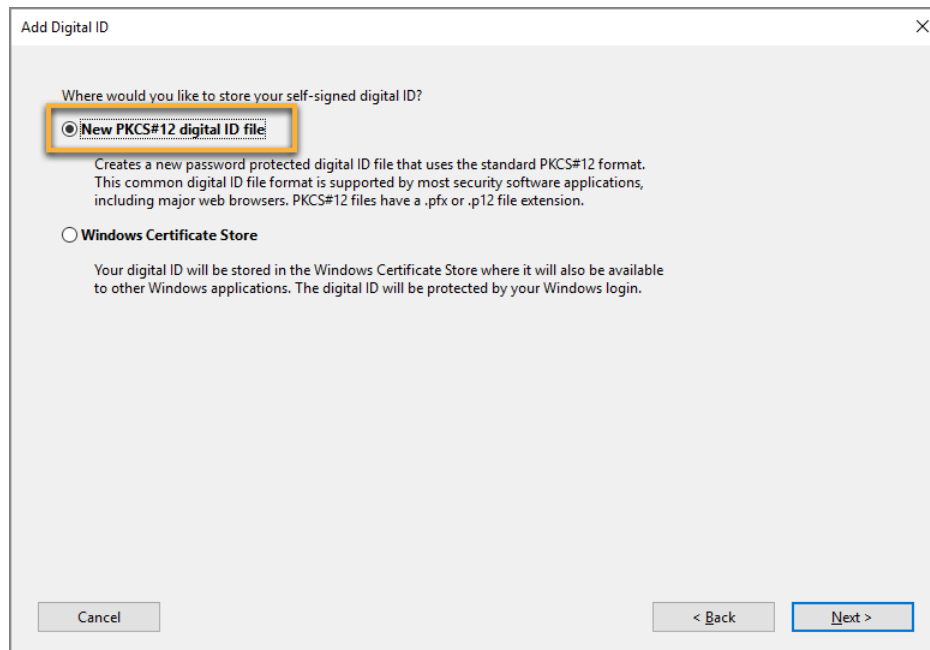3. Select **Digital IDs** on the left, and then click the **Add ID** button .

4. Select the option **A New Digital ID I Want To Create Now**, and click **Next**.

5. Select **New PKCS#12 Digital ID File** and click **Next**

6. Do the following:
   a) Type a name, email address, and other personal information for your digital ID. When you certify or sign a document, the name appears in the Signatures panel and in the Signature field.
   b) Choose an option from the **Key Algorithm** menu. The 2048-bit RSA option offers more security than 1024-bit RSA, but 1024-bit RSA is more universally compatible.
   c) From the **Use Digital ID For** menu, choose **Digital Signatures and Data Encryption**.
   d) Click **Next**.


7. Do the following:

   a) Type a password for the digital ID file. For each keystroke, the password strength meter evaluates your password and indicates the password strength using color patterns. Reconfirm your password.
   b) The digital ID file is stored at the default location as shown in the **File Name** field. If you want to save it somewhere else, click **Browse** and choose the location, but we recommend using the default location.
   c) Click **Finish**.
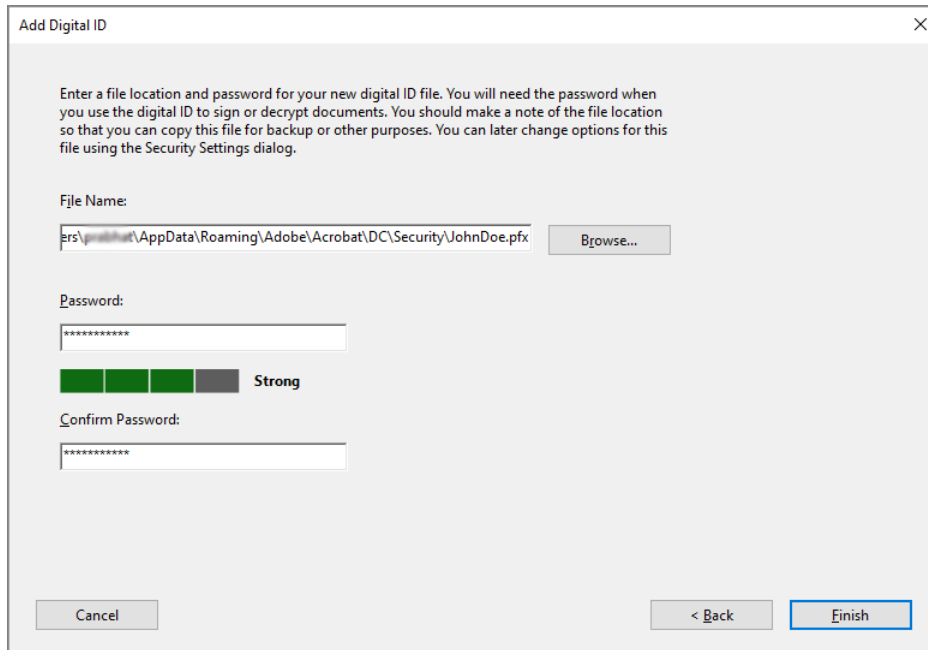
If a digital ID file with the same name exists, you're prompted to replace it. Click **OK** to replace, or browse and select a different location to store the file.

8. To make this digital ID your default, while you are still within **Preferences** > **Signatures**, click the **More** button under Identities and Trusted Certificates.
9. Click **Digital IDs** on the left, and then select the digital ID you want to use as the default.
10. Click the **Usage Options** button ✏, and select **Use for Signing**.
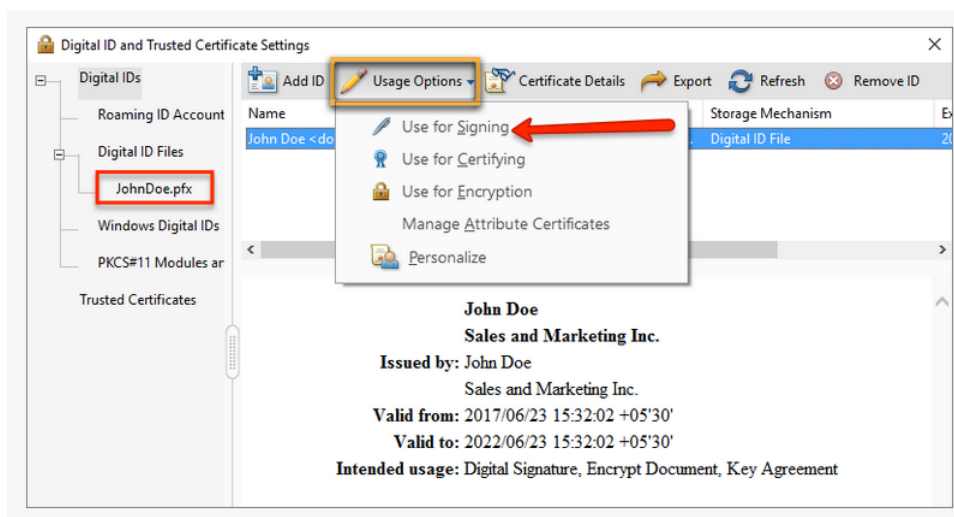
3. ADD THE CERTIFICATES TOOL IN ACROBAT:

Follow these steps to make the digital signature tool available in Acrobat. You will only need to do this once.
1. Open Adobe Acrobat
2. Click on **Tools**
3. Under **Forms and Signatures,** add **Certificates**
4. The **Certificates** tools should appear in the Tool window on the right hand side of your screen
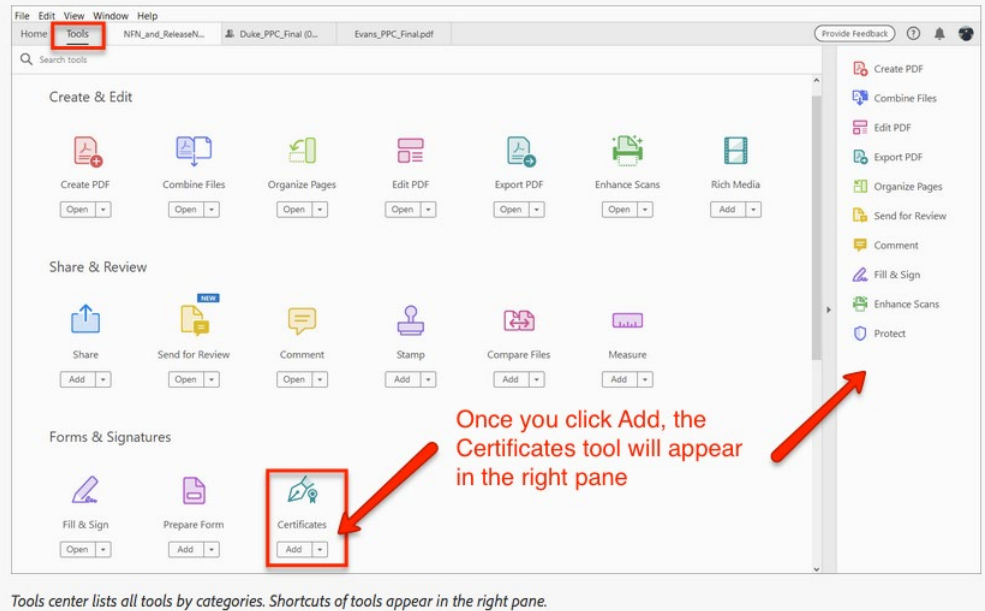
4. TO SIGN A DOCUMENT WITH YOUR SELF-SIGNED DIGITAL ID:

Follow these steps every time you need to sign a document:
1. Open Adobe Acrobat
2. Open the PDF document or form you wish to sign
3. Fill out form fields, if applicable
4. When ready to sign, click on **Certificates** in the Tools menu (right pane) and select **Digitally Sign** in the Certificates ribbon at the top of the window
   - If you are using Adobe Acrobat XI rather than Acrobat DC: click on **Fill & Sign** > **Work with Certificates** > **Sign with Certificate**
5. Drag your signature box where you want to place your signature. (Or if you are signing an Acrobat form that already has a digital signature field, just click inside that field)
6. Select the digital signature you created earlier and click **Continue**
7. Enter the password for your digital signature and then click **Sign**
8. Acrobat will prompt you to re-save your PDF and will then insert your signature

REFERENCES

- FDA Guidance: Important Information About Digital/Electronic Signatures
  https://www.fda.gov/industry/policiesguidance/important-information-about-digitalelectronic-signatures

- 21 CFR Part 11 Electronic records; Electronic Signatures
  https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=11