Monday Morning Practice Pearls #78

Is it mandatory to redact certain information from a protocol and/or consent for results reporting to ClinicalTrials.gov?

No. The Office of the Clinical Director (OCD) guidance for redacting protocols and consent for posting on ClinicalTrials.gov is not mandatory and is based on guidance for what is discoverable under Freedom of information Act (FOIA) exemptions.

The Clinical Director, Dr. James Gulley, reviews and approves the protocol and/or consent prior to uploading on the Protocol Registration and Results System (PRS) by Lisa King.

What information needs to be redacted in a protocol and/or consent?

- **Per the Freedom of Information Act (FOIA):**
  - **Exemption 4**: Trade secrets or commercial or financial information that is confidential or privileged – redacting information that is defined in a Tech Transfer agreement or other legal document as confidential, or
  - **Exemption 6:** Information that, if disclosed, would invade another individual's personal privacy – redacting personal information of study staff (i.e., phone numbers etc.)
  - **NOTE:** Principal Investigators (PI's) should not redact information not covered by the FOIA exemptions.

- **Per ClinicalTrials.gov:**
  - Information re: redacting for results reporting can be found at Frequently Asked Questions - ClinicalTrials.gov
  - Final Rule – "ClinicalTrials.gov may contact a Responsible Party (RP) if it appears that the responsible party has redacted information that is otherwise required to be submitted under these regulations." (**42 CFR 11.48(a)(5)**)

- **Additional Consideration:**
  - Consider if tech transfer, CRADA agreements, etc. allow/require redaction.

How do I redact the protocol and/or consent?

- Use Adobe Acrobat DC redaction tools, MAC PDF redaction tool or other approved software redaction tools to redact.
  - It is not recommended to use a permanent marker because redacted text may be recovered using this technique.
- To remove imbedded fonts, go to https://community.adobe.com/t5/acrobat-discussions/unable-to-remove-fonts-from-a-pdf-file/m-p/10973349)

What is the review and approval process for a redacted protocol and/or consent?

- The Principal Investigator [PI] (i.e., the Responsible Party [RP]) will send Lisa King an email an include:
    - Clean protocol and/or consent
    - Redacted protocol and/or consent
- Lisa will email the clean and redacted protocol and/or consent to the Clinical Director, Dr. Gulley, and request review and approval.
- Once Dr. Gulley approves, Lisa will email the PI to inform the redacted documents are approved.
- Lisa will upload the redacted protocol and/or consent on the PRS.

Please note: Although rare, it is possible a protocol and/or consent may encounter problems during upload due to imbedded fonts. If this occurs Lisa King will:

- Email the PI the protocol and/or consent cannot be uploaded due to imbedded fonts.
- Instruct the PI to remove the embedded fonts and return the corrected documents to Lisa King when done.

If you have any questions related to redacting the protocol and/or consent, please contact Lisa King or Liz Ness.