Frequently Asked Questions
iMedConsent™ Asynchronous Signature

1. **What is iMedConsent™?**
iMedConsent™ is a software package that supports electronic access, completion, electronically captured signature, and storage of documents, such as informed consent forms and advance directives. **VHA Handbook 1004.05, iMedCONSENT™** sets forth procedures related to the use of iMedConsent™.

   **VHA Handbook 1004.01, Informed Consent for Clinical Treatments and Procedures**, discusses the goals, scope, and key concepts related to patients’ informed consent for clinical treatments and procedures and the related responsibilities of VHA staff. Handbook 1004.01 mandates the use of the iMedConsent™ software program to document the informed consent process, except in specific circumstances.

2. **What is the relevant patch information in iMedConsent™ that includes asynchronous signature?** (For Clinical Application Coordinators)
   - Patch Name: Nabokov
   - Patch Number: 3.837.000.035
   - Release Date: December 5, 2014
   - Required Installation Date: January 30, 2015

3. **What is asynchronous signature?**
The original version of iMedConsent™ did not allow consent forms to be saved in the patient’s record, without both the practitioner’s and patient’s (or surrogate’s) signature. This has meant that unless both people are available in the same place at the same time to sign the signature pad, the informed consent form cannot be completed. The new asynchronous signature capability allows for the signatures of the practitioner and the patient (or surrogate) to be obtained at different times and/or locations. Informed consent forms can be placed on hold, allowing signatures to be obtained separately.

4. **Why was the asynchronous signature capability designed?**
The asynchronous signature capability was developed to reflect trends in telehealth, team care and clinical workflow that recognize informed consent as a process rather than an event. It was designed to allow more flexibility in the informed consent process and to make use of available communications technologies. Face-to-face interactions are not
always possible when obtaining informed consent. The asynchronous signature capability allows for the informed consent process to be completed in circumstances when the patient (or surrogate) and practitioner cannot physically be together, but are still able to directly communicate. For example, the asynchronous signature capability enables the consent form to be signed at different locations (VAMC, CBOC) following an informed consent discussion held via telephone or video.

5. **How long can a consent form be placed on hold?**
   Consent forms can be placed on hold for signature in iMedConsent™ for 60 days. This timeframe was established to make sure that the informed consent discussion and signatures are close enough in time to reasonably ensure that the patient can remember the details of the informed consent discussion. Partially signed documents will be automatically deleted after 60 days if the second signature is not applied.

6. **Does the asynchronous signature capability change the iMedConsent™ process for obtaining informed consent?**
The asynchronous signature capability does not change any processes in the consent wizards until the user clicks “sign.” After the user clicks “sign,” options are presented for signature by the practitioner and the patient (or surrogate). The practitioner may sign and “save” their signature or “skip” their signature. If “skip” signature is selected, a warning screen will be presented to the user that the signing practitioner must obtain consent from the patient (or surrogate) before signing the form.

7. **Can I edit the consent form after signing it?**
   If no signatures are “saved,” users can edit the document. If a single signature has been “saved,” users cannot edit the document unless the signature is removed. If both signatures have been “saved,” users cannot edit the document.

8. **Is there a risk associated with leaving consent forms partially signed?**
   Yes. Partially signed or unsigned consent forms are placed on hold for additional signatures by clicking “Hold for Signature” in iMedConsent™. These documents then reside in “Documents to Sign” in iMedConsent™ until final signature, or for 60 days,
whichever comes first. Placing documents on hold can be risky because there is the potential for practitioners to pull up and sign the incorrect consent form. It is important for practitioners to confirm that the document is the one they wish to sign before actually signing the document.

9. Can aspects of the informed consent process be delegated to PACT members?
Yes. Providers can delegate aspects of the informed consent process to PACT members, as appropriate to the competency of the team member. Ultimately though, the practitioner is responsible for obtaining informed consent. Patient education can be conducted by PACT members, but the practitioner MUST be involved in the informed consent discussion to ensure that the patient understands and voluntarily accepts the recommended treatment before signing the consent form.

9. Is the following an appropriate workflow for obtaining signature informed consent?
The LPN or RN completes the required education with the patient, builds the consent form and has the patient sign the consent form. The practitioner then signs the consent form. No. As stated in FAQ #8, PACT members, such as the LPN or RN, can be involved in the informed consent process, but ultimately the provider is responsible for obtaining informed consent. An appropriate workflow could entail the LPN or RN providing patient education and building the consent form, followed by the practitioner having a conversation with the veteran to answer any remaining questions and ensuring the patient’s understanding of the treatment. However, in such a workflow, neither the patient nor practitioner should sign the consent form until these steps have been completed.

Please check for updates to this FAQ document on the National Center for Ethics in Health Care’s website: http://vaww.ethics.va.gov/activities/policy.asp.

For specific ethics concerns about informed consent, please contact your local Ethics Consultation Service. For questions regarding this FAQ document, please email vhaethics@va.gov or call 202-632-8457.

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