

TVT Registry Form Changes

The below chart identifies the changes made to the previously approved TVT registry form v2.0 and the revised form v2.1 that accompanies this PRA package revision. In summary, the registry form title was revised and two data elements, each present on two pages of the form, were revised to remove two words. The rest of the form remains unchanged.

Content in v2.0	Changes in v2.1
Registry title: <i>Mitral Leaflet Clip Data Collection Form</i>	Revised title: <i>Transcatheter Mitral Valve Procedures – Leaflet Clip</i>
Data element E041 on pages 6 and 8: <i>Major Vascular Access Site Complication</i>	Data element E041 on pages 6 and 8 changed to: <i>Major Vascular Complication</i>
Data element E042 on pages 6 and 8: <i>Minor Vascular Access Site Complication</i>	Data element E042 on pages 6 and 8 changed to: <i>Minor Vascular Complication</i>

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-XXXX (Expires XX/XX/XXXX). The time required to complete this information collection is estimated to average [Insert Time (hours or minutes)] per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850. ****CMS Disclosure**** Please do not send applications, claims, payments, medical records or any documents containing sensitive information to the PRA Reports Clearance Office. Please note that any correspondence not pertaining to the information collection burden approved under the associated OMB control number listed on this form will not be reviewed, forwarded, or retained.