|  |
| --- |
| Supplemental Form: Investigational Devices |

|  |
| --- |
| Submit this form in addition to the IRB Research Proposal in IRBaccess when a study involves the use of investigational devices. |

|  |
| --- |
| Study Number |
| Click or tap here to enter text. |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Device Information | | | | |
| *Additional sections may be generated by clicking the + button to the right of the table while its contents are selected. Click in the table below to access the Repeating Section Content Control.* | | | | |
| Name | | Click or tap here to enter text. | | |
| Manufacturer | | Click or tap here to enter text. | | |
| Select all that apply | | | | |
|  | Marketed medical device being used according to FDA approved indication | |  | Investigational medical device |
|  | New use for marketed medical device | |  | Other Device |
| Device Regulatory Category | | | | |
|  | IDE Exempt (sponsor determined the device qualifies as exempt). | |  | Non-Significant Risk Device |
|  | Significant risk device | |  | |
| Select who holds the Investigational Device Exemption for the device | | | | |
|  | Not Required | |  | External to UT Sponsor or Investigator |
|  | UT Sponsor-Investigator | |  | UT Sponsor (Non-Investigator) |

|  |  |  |
| --- | --- | --- |
| Additional Documents: | | |
| For each device identified upload the following documentation as applicable: | | |
|  | Description of the device | |
|  | Reports of prior investigations conducted with the device | |
| **For IDE Exempt device, one or more of the following:** | | |
|  |  | Documentation explaining how the device meets the criteria for an IDE exemption |
|  | Communication from the sponsor verifying the IDE exemption |
|  | Communication from the FDA verifying the IDE exemption |
|  | External sponsor’s protocol explaining IDE exemption |
| **For nonsignificant risk device, one of more of the following:** | | |
|  |  | Sponsor’s protocol including a justification for the nonsignificant risk determination |
|  | Communication from the sponsor providing justification for the nonsignificant risk determination |
|  | Communication from the FDA verifying the nonsignificant risk determination |
| **For significant risk devices, one or more of the following:** | | |
|  |  | Sponsor’s protocol including IDE number |
|  | Communication from the FDA verifying the IDE number |
|  | Communication from the sponsor verifying the IDE number |