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| --- |
| **Use To Report Information Items The Use Of An Emergency Use Of An Unapproved Drug Or Biologic, Emergency Use Of An Unapproved Device, Or Compassionate Use Of An Unapproved Device Being Used Without An IDE\*** |
| **Treating Physician:** |       |
| **Primary Contact:** |       |
| **Person completing form:** |       |
| **Date of Occurrence:** |       |
| **Description of use: (Attach supporting documents to this form, including template of the Emergency Consent Form used for obtaining consent.)** |
|       |
| **In the opinion of the physician:** |
| **I have personally reviewed this information and agree with the above assessment:** |
| Signature  | Date |
|       |  |
|  |  |
| Signature of Physician Unaffiliated with the Use of the Article | Date |
|       |  |

\*Reference worksheets:

“WORKSHEET: Emergency Use Drugs and Biologics (HRP-451)”

“WORKSHEET: Emergency Use Devices (HRP-452)”

“WORKSHEET: Compassionate Use Devices (HRP-453)”

“WORKSHEET: Expanded Access Drugs and Biologics (HRP-454)”