**DEVICE SUMMARY TABLE**

*See* [*IRB-HSR Website*](https://research.virginia.edu/sites/vpr/files/2020-05/Investigational%20Medical%20Devices_05-13-20.docx) *and* [*FDA*](https://www.fda.gov/medical-devices/investigational-device-exemption-ide/expanded-access-medical-devices) *for Additional Information*

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| --- | --- | --- | --- | --- | --- |
|  | **Single Patient Expanded Access: Emergency Use** | **Single Patient Expanded Access (Non-Emergency)** | **Humanitarian Use Device (HUD) or Off Label HUD** | **Expanded Access for Large/Medium Group Treatment Use** | **Research** |
| **Background** | IMMEDIATE life-threatening situation and no time to get IRB approval**\*INCLUDES Emergency HUD\*****DOES NOT require IRB or FDA approval BEFORE use.** Sponsor must obtain a Single patient Emergency use IDE from FDA.Use: [Request for IRB Concurrence-Emergency Device](https://research.virginia.edu/sites/vpr/files/2020-04/Request%20for%20IRB%20Concurrence-Emergency%20Device.docx) | ***Not considered Immediately life threatening*** Treating physician feels device will help patient(s).Allowed before or during a clinical trial Sponsor must obtain a Single Patient treatment IDE from FDA BEFORE useUse: [Request for IRB Concurrence Non-Emergency](https://research.virginia.edu/sites/vpr/files/2020-05/Request%20for%20IRB%20Concurrence%20for%20a%20Single%20Patient%20Non-Emergency%20Treatment%20with%20an%20Investigational%20Drug%20or%20Device%205-11-20.docx) | Device that would be used in less than 4000 patients /year in the US. (Orphan Device) Sponsor must obtain a HDE # from FDA PRIOR to useUse: [HUD Information Form](https://research.virginia.edu/sites/vpr/files/2020-05/HUD%20Information%20Form_05-14-20.docx) |  Allows patients access to device after clinical trials are completed- awaiting FDA approval.Submission Via CR CONNECT and Protocol BuilderFull Board Review\*\*May use Single IRB | Use of an investigational device for research purposes**Submission via CRCONNECT and Protocol Builder****IRB** must determine if device is exempt from IDE regulations. If not exempt, must determine if device is significant risk.\*May use Single IRB |
| **Follow-Up** | Within 5 days of use submit notification to IRB using [Single Patient Treatment Follow-up](https://research.virginia.edu/sites/vpr/files/2020-05/Single%20Patient%20Treatment%20Follow-up_05-11-20.docx)Sponsor cannot submit data as part of an FDA application | Within 5 days of use submit notification to IRB using [Single Patient Treatment Follow-up](https://research.virginia.edu/sites/vpr/files/2020-05/Single%20Patient%20Treatment%20Follow-up_05-11-20.docx)Sponsor cannot submit data as part of an FDA application | No-follow UVA IRB Full Board Instructions | Follow Full Board IRB Instructions  |  Follow Full Board IRB Instructions  |
| **Considered Research?**  | No- however FDA requires an IDE# and IRB Concurrence  | No- however FDA requires an IDE# and IRB Concurrence | No, however IRB review required. | Yes | Yes |
| **CRCONNECT and Protocol Builder?** | No | No | No | Yes | Yes |
| **Protocol** | Treatment plan or protocol along with patient protections measures | Treatment plan or protocol along with patient protection measures | No, but need tosubmit Investigators Brochure | Yes- submit sponsors protocol only | Yes- may submit UVA Protocol or Sponsors protocol and IRB Application |
| **Consent** | Yes-use sponsors consent or use [UVA Template](https://research.virginia.edu/sites/vpr/files/2020-04/Humanitarian%20Use%20Device%20HUD%20Consent%204-23-20.docx) if patient able to consent. For Emergency HUD use: [UVA Consent Template](https://research.virginia.edu/sites/vpr/files/2020-04/Humanitarian%20Use%20Device%20HUD%20Consent%204-23-20.docx). | Yes-submit and use sponsors consent or [UVA template](https://research.virginia.edu/sites/vpr/files/2020-05/Emergency%20Use%20Consent_Investigational%20Drug%2C%20Biologic%2C%20Device%2010-21-19.doc) | Yes, may use sponsors template or use [UVA Consent Template](https://research.virginia.edu/sites/vpr/files/2020-04/Humanitarian%20Use%20Device%20HUD%20Consent%204-23-20.docx).  | Yes-use [UVA template](https://research.virginia.edu/sites/vpr/files/2020-05/Emergency%20Use%20Consent_Investigational%20Drug%2C%20Biologic%2C%20Device%2010-21-19.doc)  | Protocol Builder Consent Template unless waiver approved |
| **Training** | No | No | No | Yes | Yes |
| **New Medical Device if 1st time use at UVA** | Yes | Yes- | Yes | Yes | Yes |
| **Review Type and Response** | IRB Chair ConcurrenceNo continuation review For Emergency HUD- Continuations- Expedited via Category # 9 | IRB Chair Concurrence onlyNo Continuation Review | Initial – Full Board-AssuranceContinuations- Expedited via Category # 9 | Full Board -AssuranceContinuations-YES | Full Board -AssuranceContinuations-YES |