



Humanitarian Use Device Application Checklist

1 copy of each of the following documents except where noted should be delivered to our office and emailed to hrrc@salud.unm.edu.

You can download each of the forms directly from this checklist.

Required for Every Submission

	HRRC HUD Application
	Department Review Form
	Conflict of Interest forms for Every Investigator on the study Conflict of Interest form for UNM Employees or Students Conflict of Interest form for non-UNM Employees
	<i>Make sure all of the above documents are signed and filled out!</i>
	Investigators Protocol: Guidelines for developing the Protocol Sponsor's Protocol (for commercially Sponsored Study) Manufacturer's clinical brochure or informational materials
	Documentation from the UNM and/or NM VAHCS Credentialing Committee that you are 'credentialed' to use this HUD
	FDA Humanitarian Device Exemption Letter (or similar documentation)

Attachments that may be applicable

	1. Additional Investigators List
	2. Studies Involving Minors
	10. Studies Involving Prisoners
	Patient labeling information sheet, brochure, and/or Consent Form