IRB-HSR Submission Types

Unsure of the correct submission type? Contact IRB-HSR@ 243-0639 or 924-2620 to discuss.
A conversation TODAY eliminates issues TOMORROW

Emergency Use of an Unapproved Drug or Device	**Humanitarian Device Exemptions (HDE)**	**Non-Human Subject Research Determination**	**Non-UVA Agent Determination**	**Exempt Determination**	**Non-Engaged Determination** *Not applicable if FDA regulated*	**Expedited Approval** ***IRB Approval by IRB Chair/Member***	**Full Board Approval** ***IRB Approval by IRB at a convened meeting***
Emergency use of an unapproved drug or device for clinical care of a single patient.	*Exemption for use of a Humanitarian Use Device (HUD).*	*Project does not meet the definition of human subject research or a clinical investigation of a test article.*	*Involved in Human Subject Research but research is not being done on behalf of UVa.*	*Must be minimal risk and meet an Exempt Criteria (see below).*	*Research that does not meet previous Determination types and does not "engage" UVa in human subject research.*	*Must not meet previous review types, be minimal risk and meet an Expedited Criteria (see below).*	*Any protocol that does not qualify for another review type.*
If not Emergency Use →	If not use of an HUD under an HDE →	If study does not meet Determination →	If study does not meet Determination →	If study does not meet Determination →	If study does not meet Determination →	If study is not minimal risk and does not meet Expedited Criteria →	Submit an application for Full Board review
Requirements: • Patient's condition is life-threatening • No standard treatment available • There is not sufficient time to obtain IRB approval • Requires notification to IRB within 5 working days of use. • IRB provides concurrence with emergence use classification. Additional Information: Emergency Use	**Requirements:** • Requires an approved HDE from FDA • Requires prior IRB approval, but is not considered research Additional Information HDE/HUD	**Requirements:** Determination of Non-Human Subject Research	**Requirements:** Determination of Non-UVa Agent	**Requirements:** Exempt Criteria	**Requirements:** OHRP Guidance Document	**Requirements:** Expedited Criteria •If a non- UVA IRB will serve as the IRB or Record or the IRB-HSR will serve as the IRB of Record for multiple sites- see IRB Reliance Agreement section below	**Requirements:** • If a non- UVA IRB will serve as the IRB or Record or the IRB-HSR will serve as the IRB of Record for multiple sites- see IRB Reliance Agreement section below • If the study involves use of an investigational drug or device for clinical care (e.g. compassionate/ treatment use) see Expanded Access information below)

Scroll down to see EXAMPLES and HOW TO SUBMIT.

Examples: • Patient who is in a life threatening situation and does not meet the inclusion/exclusion criteria of a research protocol or the research protocol is not being conducted at UVa. No other acceptable alternative treatment available.	**Examples:** • Applies to a condition treated/diagnosed that affects fewer than 4,000 in US per year	**Examples:** • Preparatory to research and no HIPAA identifiers collected: complete Request for Medical Records Form • Use of specimens from deceased individuals • Case study (up to 3 patients) • Only using commercial cell lines • Specimens purchased from commercial supplier • Data from Public Data Set • Health Care Delivery Improvement Projects • Only using de-identified or coded data/specimens and not FDA Regulated. • Sharing data/specimens with other researchers • Medical record review and all subjects are deceased: complete: Request for Medical Records Form	**Examples:** • UVA personnel asked to assist with a research study after arriving at the non-UVA institution. • Graduate students conducting their research outside of UVA. • Person completing research at previous institution after transferring to UVa • UVa Faculty member has an appointment or clinical privileges at another institution. Research will only be conducted at outside institution.	**Examples:** • Surveys/interviews with adults that do not involve sensitive topics • Surveys/ interviews with adults that do collect sensitive information but do not record identifying information (e.g. HIPAA identifiers) • Review of medical records. Either not recording identifying information or recording identifiable information and study is regulated by HIPAA. • Research with data previously collected as part of an Improvement Project in which there was no interaction or intervention with an individual and the project only involved the use of information from UVa medical records. Data will be de-identified before sharing outside of UVA.	**Examples:** • Provide commercial or other services for researchers. • Perform clinical related procedures (e.g. x-ray or blood draw) for subject enrolled in research at another institution • Administer study drug for subject who in town on vacation. • Inform prospective subjects about research but do not obtain consent • Permit non- UVa researchers to use UVa space to conduct their research • Perform analysis on coded data/specimens from collaborators at other sites conducting the same study.	**Examples:** • One blood draw by finger stick, heel stick, ear stick, or venipuncture. *Minimal blood volumes/frequency must be met- see Expedited Criteria.* • Nasal swab that does not go beyond the nares • MRI without contrast/ ultrasound • Surveys/interviews with minors • Banking identifiable data/specimens for future unspecified research • Research with data previously collected as part of an Improvement Project in which there was no interaction or intervention with an individual & the project only involved the use of information from UVa medical records. Data will remain identifiable after sharing outside of UVA.	**Examples:** • Blood draw from existing IV, central or arterial line. • All greater than minimal risk research • Clinical trials • Any research use of radiation • Any research involving use of anesthesia • Any research use of invasive procedures • Use of viable embryos or embryonic stem cells • Planned Emergency Research including Exemption from Informed Consent (EFIC) •
Submit: Emergency Use Notification Form to the IRB-HSR within 5 days of use	**Submit:** Protocol Information Form for HUD and additional information as noted on the form to the IRB-HSR.	**Submit either:** Request for Medical Records Form to UVA Office of Health Information Services • Determination of Non-Human Subject Research Form *to the IRB-HSR (optional)*	**Submit:** Determination of Non-UVa Agent to the IRB-HSR.	**Submit:** Exempt application including required documents provided via Protocol Builder	**Submit:** Non- engaged application form provided via Protocol Builder	**Submit:** Application including required documents provided Protocol Builder	**Submit:** Application including required documents provided via Protocol Builder

Expanded Access of an Investigational Drug or Device • **Compassionate Use** • **Treatment Use**	**IRB Reliance Agreements**
(single patient/small group)	A single IRB will serve as the IRB of Record for all sites. • *IRB of Record must be accredited in most situations.*
Requirements: • Life-threatening or serious diseases • No acceptable alternative • Patient unable to participate in a clinical trial (e.g. does not meet inclusion/exclusion criteria or no clinical trial available nearby) • Drug/device under investigation in a clinical trial or all clinical trials completed • Sponsor or clinical investigator submits a protocol to the FDA • Requires an IND/IDE from FDA • Requires prior IRB approval, but is not considered research	**Examples:** • Federally funded or FDA regulated multi-center research (more than 1 U.S. site) relying on a single non-UVA IRB • All sites of a multi-site trial relying on the UVa IRB-HSR as the IRB of Record **Requirements:** An IRB Reliance/Authorization Agreement with the IRB of Record must be signed prior to relying on the non UVA IRB.

• Drugs& Biologics Additional Info: Treatment Use/ Expanded Access:
• Devices Additional Information Treatment Use/ Expanded Access:
• Health care providers may use the
  ○ UVA IRB-HSR
  ○ Western IRB
  ○ Other IRB (see IRB Reliance Agreement column)
	Submit to IRB-HSR either:
	• IRB Reliance Agreement Request Form-IRB-HSR as IRB of Record
	• IRB Reliance Agreement Request Form- non - UVA IRB as IRB of Record