<table>
<thead>
<tr>
<th>IRB-HSR Submission Types</th>
<th>Unsure of the correct submission type? Contact IRB-HSR@ 243-0639 or 924-2620 to discuss. A conversation TODAY eliminates issues TOMORROW</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Emergency Use of an Unapproved Drug or Device</strong></td>
<td><strong>Humanitarian Device Exemptions (HDE)</strong></td>
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<tr>
<td>Emergency use of an unapproved drug or device for clinical care of a single patient.</td>
<td>Exemption for use of a Humanitarian Use Device (HUD).</td>
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<tr>
<td>If not Emergency Use</td>
<td>If not use of an HUD under an HDE</td>
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<tr>
<td><strong>Requirements:</strong></td>
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<tr>
<td>• Patient’s condition is life-threatening</td>
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<tr>
<td>• No standard treatment available</td>
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<tr>
<td>• There is not sufficient time to obtain IRB approval</td>
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<tr>
<td>• Requires notification to IRB within 5 working days of use.</td>
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<tr>
<td>• IRB provides concurrence with emergency use classification.</td>
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<tr>
<td>Additional Information: Emergency Use</td>
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<tr>
<td>Additional Information: HDE/HUD</td>
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<tr>
<td>Scroll down to see EXAMPLES and HOW TO SUBMIT.</td>
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</tbody>
</table>
### 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.
- Applies to a condition treated/diagnosed that affects fewer than 4,000 in US per year.
- 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.
- 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.
- 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 a participant and the project only involved the use of information from UVa medical records. Data will be de-identified before sharing outside of UVa.
- 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.
- 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.
- 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.
- Protocol Information Form for HUD and additional information as noted on the form to the IRB-HSR.
- Request for Medical Records Form to UVA Office of Health Information Services.
- Determination of Non-Human Subject Review Form to the IRB-HSR (optional).
- Determination of Non-UVA Agent to the IRB-HSR.
- Exempt application including required documents provided via Protocol Builder.
- Non-engaged application form provided via Protocol Builder.
- Application including required documents provided via Protocol Builder.
- Application including required documents provided via Protocol Builder.
## Expanded Access of an Investigational Drug or Device

- **Compassionate Use**
- **Treatment Use**

### 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**

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*Version Date January 21, 2019*