Use this table to help you process single patient IND (SPIND) and emergency use (eIND) submissions.

General notes:

The vast majority of single patient INDs for treatment use will be new, standalone INDs.

FDA form 1571 is used when industry/UAMS is the sponsor. Industry/UAMS is typically the sponsor for SPINDs.

FDA form 3926 is used for eINDs. The physician is typically the sponsor/investigator for eINDs.

	SPIND	**eIND**
Definition	Use of investigational drug when the primary purpose is to diagnose, monitor, or treat a patient's disease or condition.	Use of investigational drug when the primary purpose is to diagnose, monitor, or treat a patient's disease or condition. AND No standard acceptable treatment available and patient in a life-threatening condition and there's no time for prior IRB review.
FDA review required?	Yes	Yes
How submitted to FDA?	Most common: New IND Also possible: Expanded access protocol under an existing IND held by company.	Most common: New IND Also possible: Expanded access protocol under an existing IND held by company.
Which FDA form used?	Form 1571 if either industry or UAMS is the IND sponsor Form 3926 if physician is the sponsor/investigator (rare at UAMS/ACH)	Form 3926 if physician is sponsor-investigator (typical UAMS/ACH scenario) 1571 if industry holds eIND (rare)
Is IRB review and/or approval required prior to use?	Yes. Review and approval.	NO. Emergency use can proceed with prior IRB acknowledgement if there is not sufficient time to secure prospective IRB review. A CLARA form is available for pre-use notification, however; sponsor may require IRB acknowledgement before shipping drug.

Does the IRB review/approval have to be from the full board?	Yes, UNLESS: Form 1571 was submitted and the submitter make a separate request for review by IRB chair/designee OR If form 3926 was submitted (rare at UAMS/ACH, as the institution or industry typically holds SPINDs) and checked box 10b	Yes, UNLESS: Physician submitted form 3926 and checks box 10b (most likely scenario at UAMS/ACH) which allows review by IRB chair/designee OR Form 1571 submitted along with a separate request for review by IRB chair/designee.
Informed consent required?	Yes, in accordance with 21 CFR 50	Yes, in accordance with 21 CFR 50 EXCEPT IF ALL OF THE FOLLOWING APPLY. (See also additional requirements in the next box.) - Both the treating MD and another MD who is not otherwise participating in the "clinical investigation" certify in writing" - The subject is confronted by a life-threatening situation necessitating the use of the test article. - Informed consent cannot be obtained because of an inability to communicate with, or obtain legally effective consent from, the subject. - Time is not sufficient to obtain consent from the subject's legal representative. - No alternative method of approved or generally recognized therapy is available that provides an equal or greater likelihood of saving the subject's life.

eIND only – if no consent is obtained, and If there is no time prior to eIND treatment for a 2nd physician to concur the four conditions above apply:	n/a	The clinical investigator should make the determination that the 4 conditions above were met, and, within 5 working days after the use of the article, have the determination reviewed and evaluated in writing by a physician who is not participating in the clinical investigation. The investigator must notify the IRB within 5 working days after the use of the test article [21 CFR 50.23(c)].
5-day follow-up report required?	No	Yes, within 5 days of initiation of treatment. There is a separate form in CLARA for this follow-up report.
HIPAA required?	Yes	Yes
What to submit to the IRB	Protocol/treatment plan; consent form, HIPAA authorization; any forms submitted to FDA; any relevant correspondence with the FDA.	Protocol/treatment plan; consent form, HIPAA authorization; any forms submitted to FDA; any relevant correspondence with the FDA. If no written consent was obtained, provide written certification by two physicians of the four conditions above under which emergency use can proceed without written consent.
Helpful reference ***See "References" section below for more links***	FDA guidance Expanded Access to Investigational Drugs for Treatment Use - Questions and Answers (FDA Guidance). ORRARegulatoryUnit@uams.edu Or RegulatoryAffairs@uams.edu	FDA Guidances: Emergency Use of an Investigational Drug or Biologic Individual Patient Expanded Access Applications: Form FDA 3926

References:

Expanded Access to Investigational Drugs for Treatment Use - Questions and Answers (FDA Guidance)

Form 3926 PDF

Form 3926 Instructions

Form 3926 Guidance

Physician Request for a Single Patient IND for Compassionate or Emergency Use (FDA Guidance) (note: UAMS or industry will typically hold the IND for non-emergency use SPINDs

21 CFR 312.300, especially 21 CFR 312.310

UAMS IRB Policy 18.3, Emergency Use of a Test Article

UAMS Office of Research Regulatory Affairs (This office acts on behalf of UAMS as Sponsor for non-emergency use INDs and can assist physicians with eINDs as well) Contact ORRARegulatoryUnit@uams.edu or RegulatoryAffairs@uams.edu