Policy	Main Description/Policy Number	Policy Title	Description of Changes
1	**Principles and Authority**		
	1.1	Principles Governing the Committee	Fix a couple formatting errors (two periods, spacing), and add language to the "any media-related queries..." section. Also added language about how this media-related queries language applies to IRB members, chairs, staff.
	1.2	Authority of the Committee	Formatting only
2	**Relationship**		
	2.3	Use of Central IRBs (Use of single/central IRBs)	Changes generally relate to what must be submitted when the UAMS Revise C12 (it's C13 now) to: Approval of protocol modifications that affect study conduct at the UAMS site Approved Informed Consent and HIPAA authorization templates that will be adapted to the UAMS site. Notification of any required continuing review approval. Determinations of serious or continuing noncompliance or of an unanticipated problem involving subjects or others that affects, or may affect, study performance at the UAMS site. Any other changes requiring another local context review at the UAMS site. “Local context review” refers to local requirements based on institutional policy or state or local law. Also add somewhere the documents required at initial submission.
6	**Documentation**		
	6.5	IRB Records	Minor edits throughout to: Reformat slightly Add language about materials and access related to xIRB reviews Amend the list of materials submitted to the IRB. Changes are not marked due to having to retype the entire policy. Original is here: https://research.uams.edu/irb/wp-content/uploads/sites/9/2022/10/IRB-Policy-6.5-IRB-Records-FINAL-1.pdf
7	**Procedures For Study Review**		
	7.3	Exempt Categories of Research	Minor grammatical changes in introductory language. Added language specifying exempt status categories do not apply to FDA regulated research. Removed specifications under each category about whether exempt status research applies.
	7.5	Expedited Review	Corrected a typo. Added language about the annual update requirement for certain expedited status studies. Deleted some references to other IRB policies.
	7.6	Continuing Review	Added language specifying a full CR form is required for FDA-regulated research even if the CR is done using expedited procedures and clarifying that CR is required for FDA-regulated research.
	7.12	Limited IRB Review	Clarified that these go through the exempt review process and that an annual update is required. Deleted "all such research is deemed to be minimal risk" since there is no regulatory requirement for exempt status research to be minimal risk.
8	**Change in Protocol**		
	8.1	Modifications to Previously Approved Research	Added langauage about how to handle modifications that include changes that were never implemented. Updated language about staff only modifications to describe current handling.

10	**Principal Investigator Responsibility**		
	10.2	Information That Must Be Reported to the IRB and IRB Actions	Added some mentions of noncompliance to this policy.
	10.3	Protocol Content and IRB Submissions	Section C3 -- Changed "with a description of their role and qualifications" to "with a description of their role and responsibilities." Additional changes made 10.10.24. Language added to Study Design and Procedures, Ethical Considerations, Statistical Plan, and Data Handling and Recordkeepoing secttions to clarify various expectations for protocol content.
12	**Quality Assurance**		
	12.6	Findings of Non-compliance under IRB Policy 12.5	Restored a missing word under B1 "determine"
14	**Recruitment Practices**		
	14.1	Selection of Subjects	Added a sentence to the POLICY section mentioning that identifying the target population and designing recruitment are factors in equitable subject selection . Tightened some language in first paragraph of PROCEDURE section. Rewrpote first "Procedure" paragraph. Original is here: https://research.uams.edu/irb/wp-content/uploads/sites/9/2022/10/IRB-Policy-14.1-Subject-Selection-FINAL.pdf
	14.2	Subject Compensation	Added mention of ensuring payments are compliant with institution policy. Added language about payment consideration when the participant needs an LAR. Moved language about coupons/discounts on study articles after approval.
	14.4	Compensation to Investigators and Health Care Workers for Enrolling Subjects	Revised to clarify: Investigators and study staff many not accept enrollment incentives in studies overseen by external IRBs. Payments to the institution to compensate for actual costs associated with enrollment and recruitment are allowed.
15	**Consent**		
	15.1	Elements of informed consent	Made minor grammatical changes in several places. Updated the IRB contact language. Clarified the IRB does not stamp consent forms.
	15.3	Waiver of Signed Informed Consent Documents and Waivers of Informed Consent Elements	Added definitions. Updated language related to FDA regulated research and waivers/alterations. Reorganized language about deception/incomplete disclosure research.
17	**Special Populations**		
	17.1	Children in Research	Changed language to clarify the UAMS IRB will not review/approve peds category 4 research, to leave open the possibility of such research overseen by other IRB being done here. Clariifed the child's signature or handwritten name sufficies as a signature on assent documents. Updated date in ward of the state language Added language about the IRB making the determination regarding the category of research.
	17.9	Prisoners Involved in Research	Added clarification that the IRB's consideration are based on those described at 45 CFR 46 Subpart C, which is the prisoner part of the Common Rule. Deliberately avoided saying we will appply Subpart C to these studies, as that language would extend the Common Rule to a study regardless of funding source, which we don't want to do.
	17.14	Planned Emergency Research	Content OK. Maybe move to section 7, Procedures for Study Review?
18	**Drugs and Devices**		

	18.3	Emergency Use of a Test Article	Changed "The IRB requires..." prior notification to "The IRB strongly encourages, but does not require... ." While sponsors typically require IRB acknowledgement before shipping the test article for emergency use, no requirement for prior IRB review appears in FDA regulations. Additional changes made 10.10.24. Added language about what to include with prior IRB notifications of emergency use.