IRB Review Level Comparison Chart

	Exempt Level of IRB Review	Expedited Level of IRB Review	Full Board Level of IRB Review
Number of IRB reviewers	Single IRB analyst	Single IRB analyst/reviewer	Review by a committee of 5-9 reviewers
Risk level of the study	Minimal risk	Minimal risk	Greater than minimal risk
Scope of IRB review	• Risk level • Application of exempt categories • Ethical standards • Institutional requirements • Consistency, completeness, accuracy of submission form/documents	• Risk level • Application of expedited categories • Federal and state regulatory requirements for human research • Institutional requirements • Consistency, completeness, accuracy of submission form/documents	• Risk level • Federal and state regulatory requirements for human research • Institutional requirements • Consistency, completeness, accuracy of submission form/documents
Approx. time until initial review comments sent	1-2 weeks	1-2 weeks	1-2 weeks
Approx. number of active protocols at VCU (July 2018)	850-950 studies (~40%)	950-1050 (~50%)	150-250 (~10%)
Types of Submissions Required after Initial Approval			
Reports	Yes	Yes	Yes
Amendments	Only certain types of changes	Yes, for all changes	Yes, for all changes
Continuing reviews	No	Only when the IRB determines that ongoing continuing review is needed	Yes
Inclusion of Regulated Vulnerable Populations			
Children	Yes, but only in exempt categories 1, part of 2, 4, 5 & 6.	Yes	Yes
Pregnant women	Yes	Yes	Yes
Prisoners	Yes, but only incidental inclusion	Yes, for certain types of research	Yes, for all types of research

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	Exempt Level of IRB Review	Expedited Level of IRB Review	Full Board Level of IRB Review
Research procedures	Education interventions & interactions Surveys Interviews (individual or group) Observations of public behavior Benign behavioral interventions Secondary research Public benefit/service program interventions & interactions	Clinical studies of some drugs/devices Blood collection within certain limits Non-invasive biological sample collection Non-invasive routine clinical procedures Moderate exercise Secondary research Surveys Interviews (individual or group) Observations Interventions & interactions of individual or group characteristics / behavior	All research procedures
FDA-regulated research	Only under exempt category 6 (taste and food quality studies)	Only when a) the test article has marketing approval and is used as approved; b) the test article is IND/IDE exempt; c) the full board determines a medical device is Non-Significant Risk; d) the full board determines a Humanitarian Use Device study can be reviewed in an expedited manner; e) post-Emergency Use reports	Yes
Radiation exposure	No	No	Yes
Randomization	Yes	Yes	Yes
Recordings	Yes	Yes	Yes
Identifiable data	Only under specific exempt categories	Yes	Yes
Consent Requirements			
Formal consent process	No	Yes, unless a waiver of consent is approved by the IRB.	Yes, except in rare instances where a waiver of consent is approved by the IRB
Informed Consent Form	No, but participants should be provided certain information when there is an opportunity. This could be within recruitment materials or Info Sheet.	Yes, all consent documents must contain specific elements of consent unless a waiver of some elements of consent is approved by the IRB.	Yes, all consent documents must contain specific elements of consent unless (rarely) a waiver of some elements of consent is approved by the IRB.