

OVERVIEW OF IRB SUBMISSIONS FOR NEW STUDIES

EXEMPT	EXPEDITED		FULL
<p>“Minimal to no risk” – Administratively reviewed. Does not require Board review.</p>	<p>“Minimal risk” – Reviewed by subcommittee.</p>		<p>“Greater than minimal risk” – Reviewed by the full Board.</p>
<p>OHR-18 OHR-5 or OHR-3</p> <p><i>Submit 1 copy of OHR forms, protocol or grant, and relevant supplementary materials (surveys, recruitment scripts, brochures, etc.)</i></p> <p><u>Examples:</u></p> <ul style="list-style-type: none"> • Survey of staff on medical practices • Retrospective review of de-identified data • Retrospective collection of de-identified tissue • Assessment of student attitudes/skills/knowledge • Patient surveys where survey subject matter is not of a sensitive nature 	<p><u>Chart/Database Review or Tissue Collection</u></p> <p>OHR-4 or OHR-15 OHR-3 or OHR-5</p> <p><i>Submit 4 collated sets of relevant OHR forms and 4 copies of protocol or grant</i></p> <p><u>Examples:</u></p> <ul style="list-style-type: none"> • Retrospective chart/database reviews with identifiers • Prospective chart/database reviews • Retrospective tissue collection with identifiers • Prospective tissue collection from tissue banks 	<p><u>Other studies</u></p> <p>OHR-1 OHR-2 OHR-15 OHR-3 or OHR-5 or OHR-8/8A/8B</p> <p><i>Submit 4 collated sets of relevant OHR forms, 4 copies of protocol/ grant and supplementary materials</i></p> <p><u>Examples:</u></p> <ul style="list-style-type: none"> • Blood draws • Non-invasive procedures (ECG, MRI, sensory testing, ultrasound, mild physical exercise, etc.) • Surveys involving protected health information • Observational studies 	<p>OHR-1 OHR-2 OHR-8/8A/8B OHR-15 OHR-16</p> <p><i>Submit 35 collated sets of OHR forms and supplementary materials, 4 copies of protocol or grant, 4 copies of device or drug brochure or package inserts</i></p> <p><u>Examples:</u></p> <ul style="list-style-type: none"> • Phase I, II, & III clinical trials involving investigational drugs or devices • Clinical trials involving investigational procedures posing greater than minimal risk • Pilot studies involving investigational drugs, devices or greater than minimal risk procedures • Studies involving vulnerable populations (children, cognitively impaired, elderly, fetuses, etc.) • Studies involving greater than minimal levels of non-physical risks (psychological, social, economic, legal)