Category 1	Clinical studies of **drugs and medical devices** only when: a) Research on drugs for which an IND is not required (21 CFR Part 312) b) Research on medical devices for which (i) an IDE is not required (21 CFR 812) OR (ii) the device is cleared/approved for marketing and is being used in accordance with its cleared/approved label	
Category 2	Collection of **blood samples** by finger stick, heel stick, ear stick, or venipuncture (a) from healthy, nonpregnant adults who weigh at least 110 lbs., or (b) from other adults and children, considering age, weight, and health of the subject, collection procedure, amount of blood & frequency of blood to be collected	(a) For healthy non-pregnant adults, the amount of blood drawn may not exceed 550 mL in an 8 week period, and collection may not occur more frequently than 2 times per week (b) for subjects (all others including children), the amount drawn may not exceed the lesser of 50 mL or 3 mL/kg in an 8 week period and collection may not occur more frequently than 2 times per week
Category 3	Prospective collection of **biological specimens** for research purposes by non-invasive means	a. Hair and nail clippings in a nondisfiguring manner b. Deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction c. Permanent teeth if routine patient care indicates a need for extraction d. Excreta and external secretions (including sweat) e. Uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gum or wax or applying a dilute citric solution to the tongue f. Placenta removed at delivery g. Amniotic fluid obtained at the time of rupture of the membrane prior to or during labor h. Supra- and subgingival dental plaque and calculus, provided collection procedure is not more invasive than routine prophylactic scaling of teeth and process is accomplished in accordance with accepted prophylactic techniques i. Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings j. Sputum collected after saline mist nebulization
Category 4	Collection of **data through noninvasive procedures** (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves	a. Physical sensors that are applied either to the surface of the body or at a distance, and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy b. Weighing or testing sensory acuity c. Magnetic resonance imaging (MRI) d. Electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow, and echocardiography e. Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight and health of the individual
Category 5	Research involving **materials (data, documents, records, or specimens) that have been collected or will be collected solely for nonresearch purposes** (such as medical treatment or diagnosis)	NOTE :Some research in this category may be exempt from the HHS regulations for the protection of human subjects (45 CFR 46.104(d)(4))
Category 6	Collection of **data from voice, video, digital, or image recordings made for research purposes**	
Category 7	Research on **individual or group characteristics or behavior** (including but not limited to research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) OR research employing **survey, interview**, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies	NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects (45 CFR 46.104(d)(2) and (d)(3)(i))
Category 8	**Continuing review** of research previously approved by the convened IRB when:	

	(a) Where (i) the research is permanently closed to enrollment of new subjects (ii) all subjects have completed all research-related interventions (iii) the research remains active only for long-term follow-up of subjects (b) Where no subjects have been enrolled AND no additional risks have been identified (c) Where the remaining research activities are limited to data analysis	
Category 9	**Continuing review of research**, not conducted under an IND application or IDE where categories 2-8 do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.	