Expedite & Exempt Cheat Sheet

EXEMPT REVIEW CATEGORIES

1. Research in Educational Setting involving Normal Educational Practices *(may apply to those under 18)*
2. Educational Tests, Survey Procedures, Interview Procedures or Observation of Public Behavior unless subjects can be identified and disclosure (* i and ii below *may apply to those under 18 for procedures involving educational tests or public observation only if investigators do not participate in the activities being observed*)
    - i. Unidentifiable / anonymous *
    - ii. Identifiable but non-sensitive *
    - iii. Identifiable and sensitive *(limited IRB review required; does not apply to those under 18; does not apply to federally funded research)*
3. Benign Behavioral Interventions (*does not apply to those under 18 or federally funded research*)
    - i. Unidentifiable / anonymous
    - ii. Identifiable but non-sensitive
    - iii. Identifiable and sensitive *(limited IRB review required; does not apply to federally funded research)*
4. Collection/Study of Existing Data, Documents, Records, Pathological/Diagnostic Specimens and subjects cannot be identified *(may apply to those under 18)*
    - i. Identifiable private information or biospecimens that are publicly available
    - ii. Information recorded without identifiers (no coding) and no intent to contact or re-identify
    - iii. Receipt/Use of PHI provided by a HIPAA covered entity *(limited dataset only and a data use agreement is required; does not apply to federally funded research)*
    - iv. Secondary research conducted by or on behalf of a federal entity *(does not apply to federally funded research)*
5. Public Benefit or Service Programs *(may apply to those under 18)*
6. Taste & Food Quality Evaluation & Consumer Acceptance Studies *(may apply to those under 18; does not apply to federally funded research)*
7. Storage and Maintenance of Identifiable Private Information or Biospecimens for Potential Secondary Use *(limited IRB review required; may apply to those under 18; does not apply to federally funded research)*
8. Use of Identifiable Private Information or Biospecimens for Secondary Research *(limited IRB review required; may apply to those under 18; does not apply to federally funded research)*

MAXIMUM AMOUNT OF BLOOD TO BE DRAWN ON PEDIATRIC

Patient Weight		Max. Vol Per 24 hrs	Max. Amount During a Hospital Stay of ≤1 month
lb	kg	ml	ml
<2	<0.9	1	8
2-4	0.9-1.8	1.5	12
4-6	1.8-2.7	2	17
6-8	2.7-3.6	2.5	23
8-10	3.6-4.5	3.5	30
10-15	4.5-6.8	5	40
16 - 20	7.3-9.1	10	60
21 - 25	9.5-11.4	10	70
26 - 30	11.8-13.6	10	80
31 - 35	14.1-15.9	10	100
36 - 40	16.4-18.2	10	130
41 - 45	18.6-20.5	20	140
46 - 50	20.9-22.7	20	160
51 - 55	23.2-25.0	20	180
56 - 60	25.5-27.3	20	200
61 - 65	27.7-29.5	25	220
66 - 70	30.0-31.8	30	240
71 - 75	32.3-34.1	30	250
76 - 80	34.5-36.4	30	270
81 - 85	36.8-38.6	30	290
86 - 90	39.1-40.9	30	310
91 - 95	41.4-43.2	30	330
96 - 100	43.6-45.5	30	350

EXPEDITED REVIEW CATEGORIES

1. Clinical studies of drugs and devices when (a) IND not required for drug or (b) IND not required for device
2. Collection of blood samples
3. Prospective collection of biological specimens for research purposes by noninvasive means
4. Collection of data through noninvasive procedures routinely employed in clinical practice, excluding procedures involving x-rays or microwaves
5. Research involving materials that have been collected, or will be collected solely for non-research purposes
6. Collection of data from voice, video, digital, or image recordings made for research purpose
7. Research on individual or group characteristics or behavior or research employing survey, interview, oral history, focus group, program evaluation human factors evaluation, or quality assurance methodologies
8. Continuing review of research previously approved by the convened IRB as follows:

    (a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or
    (b) where no subjects have been enrolled and no additional risks have been identified; or

(c) where the remaining research activities are limited to data analysis.

9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (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.

ELEMENTS OF INFORMED CONSENT

1. A statement that the study involves research, an explanation of the purposes of the research, expected length of the subject's participation, a description of the procedures to be followed, and identification of experimental products
2. A description of any risk or discomforts to the subject
3. A description of any benefits to the subject or to others expected from the research
4. A disclosure of alternative procedures or courses of treatment available to the subject
5. A statement describing the extent to which confidentiality of records identifying the subject will be maintained and that indicates the possibility that external regulatory agencies may inspect the records
6. For research involving more than minimal risk, an explanation as to whether any compensation and/or medical treatments are available if injury occurs, what they consist of or where further information may be obtained. Also, an explanation of whom to contact with questions about the research and research subject's rights, and whom to contact in the event of a research-related injury
7. A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled

WAIVER OF <u>WRITTEN</u> CONSENT
(a.k.a. Approval of Verbal Consent)

An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

(1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

(2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

IND EXEMPTION

The clinical investigation of a marketed drug or biologic does not require submission of an IND if all six of the following conditions are met:

(1) it is not intended to be reported to FDA in support of a new indication for use or to support any other significant change in the labeling for the drug;

(2) it is not intended to support a significant change in the advertising for the product;

(3) it does not involve a route of administration or dosage level, use in a subject population, or other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug product;

(4) it is conducted in compliance with the requirements for IRB review and informed consent [21 CFR parts 56 and 50, respectively];

(5) it is conducted in compliance with the requirements concerning the promotion and sale of drugs [21 CFR 312.7]; and

(6) it does not intend to invoke 21 CFR 50.24.

WAIVER (OR ALTERATION) OF CONSENT
(a.k.a. No Consent)

An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the IRB finds and documents that:

(1) The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and

(2) The research could not practicably be carried out without the waiver or alteration.

(d) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

(1) The research involves no more than minimal risk to the subjects;

(2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;

(3) The research could not practicably be carried out without the waiver or alteration; and

(4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.