Full Board Cheat Sheet

BOARD ACTIONS

Approval – the study approved as submitted.

Approved with Stipulations – the documents require minor revisions such as wording changes or administrative changes.

Deferral – study lacks sufficient information to conduct an adequate review; or substantive issues regarding the study must be addressed. Full IRB review of the investigator's response is required. The study will be placed on the next agenda once the requested information is received.

Disapproval – questions are of such significance that the IRB feel approval of the study is unwarranted. Full IRB review of the investigator's response is required for approval.

REQUIRED ELEMENTS OF INFORMED CONSENT

1. A statement that the study involves research, an explanation of the purposes of the research, expected length participation, a description of the procedures, 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 treatment.
5. A statement describing the confidentiality of records and 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, refusal to participate and discontinuing participation will involve no penalty or loss of benefits to which the subject is otherwise entitled.

EXAMPLES OF MINIMAL RISK PROCEDURES

- hair and nail clippings in a nondisfiguring manner;
- teeth at time of exfoliation or if routine required extraction;
- external secretions (including sweat);
- saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue;
- placenta removed at delivery; amniotic fluid obtained at the time of rupture or during labor;
- dental plaque, provided the collection is not more invasive than routine scaling of the teeth and the

EXAMPLES OF MINIMAL RISK PROCEDURES – Cont.

- process is in accordance with accepted prophylactic techniques;
- mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;
- sputum collected after saline mist nebulization.
- physical sensors applied 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;
- weighing or testing sensory acuity;
- magnetic resonance imaging (MRI);
- ECG, EEG, or , echocardiography;
- thermography;
- detection of naturally occurring radioactivity;
- electroretinography;
- ultrasound;
- diagnostic infrared imaging;
- doppler blood flow; or
- moderate exercise where appropriate, given age, weight, and health of the individual.

MAXIMUM AMOUNT OF BLOOD TO BE DRAWN IN HEALTHY PEDIATRIC PATIENTS

Amounts for sick children are determined by clinical judgment

PATIENT WEIGHT		MAXIMUM VOLUME PER 24 HRS
lb	kg	ml
<2	<0.9	3
2-4	0.9-1.8	4.5
4-6	1.9-2.7	6
6-8	2.8-3.6	7.5
8-10	3.7-4.5	10.5
10-15	4.6-6.8	15
15-20	6.9-9.1	30
20-25	9.2-11.4	30
25-39	11.5-13.6	30
30-35	13.7-15.9	30
35-40	16.0-18.2	30
40-45	18.3-20.5	60
45-50	20.6-22.7	60
50-55	22.8-25.0	60
55-60	25.1-27.3	60
60-65	27.4-29.5	75
65-70	29.6-31.8	90
70-75	31.9-34.1	90
75-80	34.2-36.4	90
80-85	36.5-38.6	90
85-90	38.7-40.9	90
90-95	41.0-43.2	90
95-100	43.3-45.5	90

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RISK LEVELS – SPECIAL FINDINGS CHILDREN

§46.404: No greater than minimal risk and adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, one parent signs.

§46.405: Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subject, one parent signs.

§46.406: Research involving greater than minimal risk but presenting no prospect of direct benefit to the individual subjects but likely to yield generalizable knowledge about the subject's disorder or condition, both parents sign (Unless one parent is deceased, unknown, incompetent, not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.)

§46.407: Research not otherwise approvable but presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children. The IRB will advise the investigator that a request to consider approval of the research must be made to the Secretary of Health and Human Services, through the IRB. If requested, the Secretary will convene a panel of experts to review the research for inclusion of children.

RISK LEVELS – SPECIAL FINDINGS PREGNANT WOMEN AND FETUSES

§46.204: The IRB found that appropriate preclinical studies have been done; risk is the least possible to achieve study objectives; there is direct benefit to the women or fetus or if no direct benefit, the risk to the fetus is no more than minimal and the knowledge can't be obtained by other means; there is no incentive that will be offered to terminate the pregnancy; investigators will have no part in the decisions regarding the pregnancy termination or fetal viability; and there are adequate provisions to obtain informed consent (consent from the father, if available, is required if the benefit is solely to fetus.)

§46.205: The research involving neonates. IRB found preclinical studies have been done, investigators do not have any part in the decisions regarding the viability of the neonate and there are adequate provisions to obtain informed consent. In addition, if applicable

- Neonates of uncertain viability - Either research holds out prospect for enhancing viability or no added risk and consent from either parent allowed.
- Nonviable neonate - Vital functions not artificially maintained; research will not terminate heartbeat or respiration; no added risk, knowledge that cannot be obtained by other means; and consent from both parents is required.

§46.207: The research involves pregnant women, fetuses or neonates and was found by the IRB to otherwise not be approvable but presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of pregnant women, fetuses or neonates. The IRB will advise the investigator that a request to consider approval of the research must be made to the Secretary of Health and Human Services, through the IRB. If requested, the Secretary will convene a panel of experts to review the research.

PRISONER RESEARCH

§46.305: The IRB found that the research is in one of the permissible categories; advantages from the research are not coercive; risk equal to the risk acceptable to non prisoners; information understandable to subject population; no effect on parole; and if applicable, appropriate provisions for follow-up after release.

Permissible Categories:

- Study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects.
- Study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects.
- Research on conditions particularly affecting prisoners as a class (only after special panel.)
- Research which has the intent and reasonable probability of improving the health or well-being of the subject (control groups require special panel.)

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.