Office of Human Research Ethics Training Tips
Regulatory Findings Documentation, December 2016

Waivers

☐ **HIPAA-limited waiver** (B.2.1) Investigator-provided justification and limitations acceptable? ☐ Yes ☐ *No

PI must provide specific PHI that they need & why they need it for this study. Not a hunting license to get everything, just in case they need it. Limited to exactly & only what they can justify needing without getting subject's authorization.

☐ **HIPAA-full waiver** (D.3.1) Investigator-provided justification and limitations acceptable? ☐ Yes ☐ *No

☐ **Consent-waiver written** (D.3.1) Investigator-provided justification and limitations acceptable? ☐ Yes ☐ *No (Not applicable to FDA-regulated research beyond pre-screening.)

☐ **Waiver of Elements of Consent (D.3.1)** Investigator-provided justification and limitations acceptable? ☐ Yes ☐ *No (Not applicable to FDA-regulated research.)

☐ **Consent-full waiver** (D.3.1) Investigator-provided justification and limitations acceptable? ☐ Yes ☐ *No (Not applicable to FDA-regulated research.)

☐ **Waive of minor assent** (child unable to provide assent OR prospect of benefit not available outside of research)

Study-specific justification for waiver of minor assent: Click here to enter text.

You MUST site protocol specific reasons that justify waiver of a minor assent, i.e., study of young infants with "X" who unable to understand or provide assent;

If the waiver applies to only some of the participants or only parts of the research, describe here:

Click here to enter text.

Requirements for Waiver or Alternation of Consent

1. **Minimal Risk,**
2. **Identifiers**
3. **NO PHI!**

"Research could not practicably carried out without the waiver or alternation;"

Requirements for waiver of documentation of consent

1. **Minimal Risk**
2. **Documentation is risk for the subject**
3. **Written consent would not be requested outside research**
4. **NO PHI**

Not an option for FDA regulated research

Research involving CHILDREN

☐ **46.404/50.51**, Research not involving greater than minimal risk. (1 parent's signature) OR

☒ **46.405/50.52**, Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects. (1 parent's signature) OR

☐ **46.406/50.53**, Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition. (2 parent's signatures)

☐ **46.407/50.54**, Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.

AND, if applicable↓

☐ **46.409/50.56,** Children who are wards of the state or any other agency, institution, or entity can be included if research is related to status as Ward OR Conducted in Schools, Hospitals, or similar settings in which a majority of the children are NOT Wards.

It is required that the risk level determination recommendation made by the primary reviewer is based on study specific reasons, then discussed by the IRB and voted on to agree or change the primary reviewer's recommendation. The recommendation MUST be based on the risk: benefit ratio of the study citing protocol specific design as documentation of the greatest risk to the child posed by the study and how those risks are minimized by the study design. For example, the greatest risk to the child is exposure to the study drug, but holds prospect of possible benefit for the child for their "X" disease/condition and the furthering of knowledge about this disease. The risks are minimized by close monitoring of the child, stopping rules and frequent testing.

Study-specific justification: Click here to enter text.

Research involving PREGANT WOMEN, FETUSES

☐ **46.204(d)** The research holds out the prospect of direct benefit to the pregnant woman, the prospect of a direct benefit both to the pregnant woman and the fetus, **or** no prospect of benefit for the woman nor the fetus when risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means. Requires consent of pregnant woman only.

☐ **46.204(e)** The research holds out the prospect of direct benefit solely to the fetus. Requires consent of the pregnant woman and the father except if the father is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest.

Must provide study specific reasons to justify inclusion of pregnant women in research studies. For example, there is no study drug or device included in this study and thus no danger posed to the pregnant woman or her fetus. Or study drug is an approved drug for adults and cannot pass the blood/placenta barrier and pose a risk to the fetus.

Study-specific justification: Click here to enter text.

FDA-regulated research

☐ Study exempt from IDE (investigational device) requirements.

☐ Investigational device; study meets criteria for Non-significant Risk (NSR)—(Abbreviated IDE)

Study-specific justification: Click here to enter text.

☐ Study exempt from IND (investigational drug) requirements.

☐ Investigational device; study conducted under IDE (IDE#)

☐ Investigational drug; study conducted under IND (IND#)

Notes: Click here to enter text.

REVIEWER RECOMMENDATIONS

☐ Approval **without stipulations** ☐ Contingent approval (**with stipulations**)

☐ Deferral ☐ Disapproval

☐ **Category 9** Continuing review of research not conducted under IND/IDE; the IRB determines that this study involves no greater than minimal risk and no additional risks identified—Future reviews may be reviewed by expedited review.

Review Period ☐ 12 months ☐ 6 months ☐ 3 months ☐Other: