

Examples of Documenting “Determinations Required by the Regulations and Protocol- Specific Findings Justifying Those Determinations”

Research involving children

The IRB determined that (1) the research was of greater than minimal risk because it involved the administration of chemotherapy, (2) the procedures held out the prospect of direct benefit for each individual participant because every child is getting standard therapy or standard therapy plus an investigational drug, (3) The risk is justified by the anticipated benefit to the participants because children are either getting standard therapy, and initial data suggest potential efficacy of the investigational drug, and (4) the relation of the anticipated benefit to the risk is at least as favorable to the participants as that presented by available alternative approaches as all treatment arms include standard therapy. The IRB determined that the permission of each child’s parents or guardian is required unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child. The IRB agreed that if one parent is traveling and treatment cannot be delayed, that the parent can be considered not reasonably available. The IRB determined that assent is not required because the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, since these children all have cancer and the investigational drug is unavailable outside the research.

Waiver of Consent

The IRB (or reviewer) determined that (1) the research involves no more than minimal risk to the participants because the main risk is a breach of confidentiality and procedures are in place to make such breaches very unlikely; (2) the waiver or alteration will not adversely affect the rights and welfare of the participants because there are no laws that specifically require consent and the information collected is not sensitive; (3) the research could not practicably be carried out without the waiver or alteration because the participants would be difficult to locate by the time it was clear that they had the disease being studied, and the rarity of the event makes it unreasonable to consent all people who enter the hospital; and (4) the participants will not be provided with additional pertinent information after participation for the same reason as in (3). In addition, the IRB (or reviewer) confirmed that the research is not FDA regulated.

Waiver of Consent Documentation

The IRB (or reviewer) determined that (1) the only record linking the participant and the research would be the consent document because after the collection of the tissue no other identifying data are being recorded, and (2) the principal risk would be potential harm resulting from a breach of confidentiality because there are no other interventions or interactions with the participant other than the collection of tumor specimens that would otherwise be discarded by pathology. The protocol indicates that the investigator will ask each participant whether the participant wants documentation linking the participant with the research, and that the participant’s wishes will govern. The investigator has provided a consent document to be used for this purpose. In addition, the IRB (or reviewer) confirmed that the specific research to be done on these tumor specimens is not FDA regulated.

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Waiver of Consent Documentation

The IRB (or reviewer) determined that (1) the research presents no more than minimal risk of harm to subjects because the procedure is telephone screening to determine if individuals are eligible for a study, and no sensitive information will be collected, and (2) involves no procedures for which written consent is normally required outside of the research context as written documentation of consent is not required for telephone screening.

Research involving prisoners

The IRB determined that:

- (1) the research under review represents research on hepatitis B, which is a condition particularly affecting prisoners as a class and that the study will proceed only after the Secretary of DHHS has consulted with appropriate experts including experts in penology, medicine, and ethics, and published notice, in the Federal Register, of his intent to approve such research;
- (2) there are no advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, so that the prisoner’s ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is not impaired;
- (3) the risks involved in the research are primarily a breach of confidentiality of the medical record and data collection which are commensurate with risks that would be accepted by non-prisoner volunteers;
- (4) procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners because the research will be open to any prisoner who wishes to volunteer.
- (5) the information is presented in language which is understandable to the subject population because the individuals obtaining consent are experienced in communicating with prisoners and the consent document has been reviewed to make sure it is at an appropriate reading level for prisoners;
- (6) adequate assurance exists that parole boards will not take into account a prisoner’s participation in the research in making decisions regarding parole as provided by a letter from the prison to this effect, and the consent process and consent document will inform each prisoner in advance that participation in the research will have no effect on his or her parole; and
- (7) where the Board found that there may be a need for follow-up examination or care of participants after the end of their participation. Adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners’ sentences, because the investigator has indicated that he will refer these individuals to other physicians who can provide care and continue to collect data for research purposes. The consent process and consent document will inform participants of these provisions.