

## **Document 83: Element II.3.A**

(02/25/09)

### **Policies and Procedures for Maintaining Complete Files**

IRB recordkeeping will comply with regulatory requirements (45 CFR §46.115 (a)-(b) and 21 CFR §56.115(a)-(b), and VHA's Records Control Schedule (RCS 10-1)).

IRB records will be retained in the Office of Research Compliance or in the electronic system and will include copies of:

- All research proposals reviewed
- Any scientific evaluations of research proposals
- DHHS-approved sample consent documents.
- Progress reports submitted by investigators
- Reports of injuries to participants
- Minutes of IRB meetings
- Records of continuing review activities
- Correspondence between the IRB and the investigators
- A list of IRB members with complete CV or resume'
- Procedures for the IRB.
- Statements of significant new findings provided to participants

IRB records for a protocol are organized to allow a reconstruction of a complete history of all IRB actions related to the review and approval of the protocol.

IRB records clearly indicate what the IRB actually approved.

IRB records are accessible for inspection and copying at reasonable times and in a reasonable manner.

IRB records (minutes) must document (a) each of the determinations required by the regulations and (b) for each determination information specific to the protocol that justifies that determination for each of the following categories:

1. Research involving children.
2. Research involving prisoners.
3. Research involving pregnant women and fetuses.
4. Waivers or alterations of the consent process.

#### **Research involving children**

The IRB determined:

1. risk level evaluation (categories 1-4);
2. parental consent;
3. if children are wards of state;
4. if assent will be required;
5. if documentation of assent is required; and
6. the parental consent method to be used.

#### **Waiver of Consent**

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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;
3. the research could not practicably be carried out without the waiver or alteration; and
4. whether the participants will be provided with additional pertinent information after participation.
5. 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 research is not FDA regulated.

### **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 a single blood draw from health persons; 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 a blood draw.

### **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;

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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.

IRB records for all exemption determinations include citation of the specific category justifying the exemption.

The IRB records for each study's initial and continuing review notes the frequency (not to exceed one year) for the next continuing review in months or other conditions that may have been imposed by the IRB.

For VAMC research, all required records, must be maintained for a minimum of 5 years after the completion of the study.

For VAMC research, all correspondence between the IRBs and the Office of Research Compliance and the VA Research and Development Committee will be retained.

For VAMC research, all unexpected adverse events that have been submitted to the IRB and all protocol violations that have been submitted to the IRB will be retained

The WVU Office of Research Compliance has adopted the BRAAN II process for handling human subject research. With this system, all documents, including previously approved consent forms, will be retained electronically.