



1. VA MEDICAL CENTER

STATION NO.

NAME AND LOCATION (CITY, STATE)

2. VA PRINCIPAL INVESTIGATOR

LAST NAME, FIRST NAME, MIDDLE INITIAL

DEGREES

VA PAID STATUS

FULL ADDRESS FOR EXPRESS OR COURIER DELIVERY

TELEPHONE

FAX

E-MAIL

3. ACOS FOR RESEARCH AND DEVELOPMENT

LAST NAME, FIRST NAME, MIDDLE INITIAL

DEGREES

FULL ADDRESS FOR EXPRESS OR COURIER DELIVERY

TELEPHONE

FAX

E-MAIL

4. TISSUE BANK

NAME OF TISSUE BANK

ADDRESS OF TISSUE BANK

URL OF TISSUE BANK WEB SITE

5. TISSUE BANK DIRECTOR

LAST NAME, FIRST NAME, MIDDLE INITIAL

DEGREES

FULL ADDRESS FOR EXPRESS OR COURIER DELIVERY

TELEPHONE

FAX

E-MAIL

6. INFORMATION ABOUT THE STUDY COLLECTING BIOSPECIMENS

TITLE OF THE STUDY		NO. OF SUBJECTS YOU PLAN TO ENROLL AT THIS SITE:
<input type="text"/>		<input type="text"/>

STUDY SPONSOR	GRANT OR AWARD NO.	START DATE
<input type="text"/>	<input type="text"/>	<input type="text"/>
		END DATE
		<input type="text"/>

TYPES(S) OF BIOSPECIMENS COLLECTED AND STORED (E.G., BLOOD, LUNG TISSUE, BUCCAL SWAB, DNA)	HOW LONG WILL THE BIOSPECIMENS BE HELD?
<input type="text"/>	<input type="text"/>

DOES THE INFORMED CONSENT UNDER WHICH THE BIOSPECIMENS WERE COLLECTED ALLOW STORAGE FOR FUTURE RESEARCH OR A SPECIFIC TYPE OF RESEARCH? (E.G. ANY STUDY ON THIS DISEASE/CONDITION, ANY FUTURE STUDY, GENETIC STUDIES, ETC.)	IS IRB AND R&D COMMITTEE APPROVAL CONTINGENT UPON THIS WAIVER?
<input type="text"/>	<input type="radio"/> YES <input type="radio"/> NO

THE BIOSPECIMENS SHOULD BE LABELED WITH A CODE THAT DOES NOT CONTAIN THE SUBJECT'S NAME, INITIALS, SSN, OR ANYTHING DERIVED FROM THE ELEMENTS OF A SUBJECT'S PROTECTED HEALTH INFORMATION LISTED BELOW.

PROTECTED HEALTH INFORMATION

- ▶ NAMES AND INITIALS
- ▶ ALL GEOGRAPHIC SUBDIVISIONS SMALLER THAN A STATE
- ▶ ALL ELEMENTS OF DATES (EXCEPT YEAR) FOR DATES DIRECTLY RELATED TO AN INDIVIDUAL
- ▶ TELEPHONE NUMBERS
- ▶ FAX NUMBERS
- ▶ E-MAIL ADDRESSES
- ▶ SOCIAL SECURITY NUMBERS OR PARTS OF THEM
- ▶ MEDICAL RECORD NUMBERS
- ▶ HEALTH PLAN BENEFICIARY NUMBERS
- ▶ ACCOUNT NUMBERS
- ▶ CERTIFICATE/LICENSE NUMBERS
- ▶ VEHICLE IDENTIFIERS AND SERIAL NUMBERS, INCLUDING LICENSE PLATE NUMBERS
- ▶ DEVICE IDENTIFIERS AND SERIAL NUMBERS
- ▶ WEB URLS
- ▶ INTERNET PROTOCOL (IP) ADDRESS NUMBERS
- ▶ BIOMETRIC IDENTIFIERS, INCLUDING FINGERPRINTS AND VOICEPRINTS
- ▶ FULL-FACE PHOTOGRAPHIC IMAGE
- ▶ ANY OTHER UNIQUE IDENTIFYING NUMBER

6. INFORMATION ABOUT THE STUDY COLLECTING BIOSPECIMENS, con't

THE CODE USED TO LINK THE BIOSPECIMENS TO THE SUBJECT'S IDENTITY MUST BE MAINTAINED AT THE VA FACILITY. IF A COPY OF THE CODE NEEDS TO BE STORED ELSEWHERE, INDICATE WHERE AND WHY.

DESCRIBE THE CODING SYSTEM USED. (E.G., STUDY SITE NUMBER FOLLOWED BY A HYPHEN AND 5 RANDOM NUMBERS AND LETTERS)

WHO HAS ACCESS TO THE CODE? (PI, STUDY COORDINATOR, DATA COORDINATION CENTER DIRECTOR, ETC.)

HOW ARE THE BIOSPECIMENS SECURED? (LOCKED FREEZER, LOCKED ROOM, ETC.)

WILL CLINICAL AND/OR DEMOGRAPHIC DATA RELATED TO THE BIOSPECIMENS BE SENT TO THE TISSUE BANK AND/OR DATA COORDINATION CENTER (DATA REPOSITORY)?

- YES, TO THE TISSUE BANK
- YES, TO THE DATA COORDINATION CENTER
- YES, TO BOTH THE TISSUE BANK AND DATA COORDINATION CENTER
- NO

IF YES, HOW ARE THE DATA LABELED? (E.G., CODE USED FOR BIOSPECIMEN)

IF YES, LIST WHAT DATA WILL BE SENT? (X-RAYS, CT SCAN, MEDICAL HISTORY, ETC.)

HOW ARE THE DATA SECURED? (PASSWORD-PROTECTED DATABASE, FIREWALL, ETC.)

7. ADDITIONAL INFORMATION

PROVIDE THE JUSTIFICATION FOR ESTABLISHING A TISSUE BANK AND FOR BANKING BIOSPECIMENS AT A NON-VA REPOSITORY.

EXPLAIN THE BENEFITS OF THE TISSUE BANK TO VETERANS, THE VA INVESTIGATOR(S)' RESEARCH PROGRAM, AND THE VA MEDICAL CENTER.

WILL ALL FUTURE USES OF VA BIOSPECIMENS BE DONE THROUGH VA-APPROVED PROTOCOLS?

YES NO

IF NO, PROVIDE A CLEAR DESCRIPTION OF THE REASONS AND THE MECHANISMS USED BY THE BANK TO DISTRIBUTE BIOSPECIMENS TO RESEARCHERS, INCLUDING A DESCRIPTION OF THE OVERSIGHT.

PROVIDE A WRITTEN ASSURANCE INDICATING THAT UPON TERMINATION/CLOSING OF THE BANK, ALL VETERANS' BIOSPECIMENS WILL BE DESTROYED OR RETURNED TO THE ORIGINATING VA FACILITY.

PROVIDE A WRITTEN ASSURANCE INDICATING THAT THE BIOSPECIMENS AND ALL LINKS TO CLINICAL AND PERSONAL DATA CAN BE DESTROYED UPON THE REQUEST OF THE DONATING HUMAN SUBJECT.

8. ATTACHMENTS

USING THE COMMENTING TOOLS ON ADOBE ACROBAT READER ATTACH THE FOLLOWING DOCUMENTS TO THIS FORM.

- BIOGRAPHICAL SKETCH OF THE PI
- RESEARCH PROTOCOL
- A COPY OF THE MANUAL FOR THE TISSUE BANK. THIS MANUAL SHOULD PROVIDE SUFFICIENT INFORMATION REGARDING THE BANK'S POLICY, MECHANISMS OF TISSUE ACQUISITION AND REDISTRIBUTION, AND ALL OVERSIGHT MECHANISMS IN PLACE.

FAX, MAIL OR ATTACH SCANNED COPIES OF THE FOLLOWING SIGNED DOCUMENTS (see contact information below).

- RECENT IRB APPROVAL LETTER*
- R&D COMMITTEE APPROVAL LETTER*
- IRB APPROVED AND STAMPED CONSENT FORM*

**IF IRB AND R&D COMMITTEE APPROVAL ARE CONTINGENT UPON THIS WAIVER, PLEASE SEND US THE MOST RECENT VERSION OF THE CONSENT FORM. WE CAN PROVIDE A WAIVER THAT BECOMES EFFECTIVE UPON RECEIPT OF THE IRB APPROVAL LETTER, R&D COMMITTEE APPROVAL LETTER, AND IRB APPROVED AND STAMPED CONSENT FORM. THE WAIVER WILL BE REVOKED IF THESE FORMS ARE NOT RECEIVED IN 90 DAYS.*

FOR INFORMATION CONTACT: *MARILYN J. MASON, PH.D.*
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