The Insulators' Tissue Bank

International Association of Heat and Frost Insulators and Allied Workers
Est. 1903

Mount Sinai

Icahn School of Medicine at Mount Sinai
IRB Approved
Program for the Protection of Human Subjects

Andrew C. Todd, Ph.D., andy.todd@mssm.edu, Tel. 212-824-7053 / 646-438-0597

What *is* a tissue bank?

- a tissue bank (also known as a biorepository) is simply a collection of tissues
  - tissues are collected from volunteers only
- tissue banks then prepare and distribute the tissues they receive for use by medical researchers

- (The ITB will be supporting research; we will not be performing research)

Why create The Insulators' Tissue Bank?

- because medical researchers need tissue (blood and tumor tissue) to advance their research into:
  - understanding how asbestos causes disease (especially mesothelioma and lung cancer) and how that disease progresses
    - the better they understand how asbestos causes disease, the better they can develop ways to detect and treat
    - 'how' extends to why two people with the same exposure do not necessarily both get ill (this area of study is called 'susceptibility')
  - detecting disease earlier
    - the earlier they can detect, the more they can do to treat (especially for lung cancer)
  - better treatment(s) and cure(s)
    - including 'responsiveness to treatment' (why two people with the same disease do not respond identically to the same treatment) and 'personalized treatment' (the best treatment for you is not necessarily the best treatment for me)

Why create The Insulators' Tissue Bank?

- because excised tissue* acquired at many small, community-based hospitals is simply discarded
    - this is a tremendous loss to medical research advancement
- because half or more of insulators do not go to major metropolitan medical centers for diagnosis and treatment
- because insulators are unique in the magnitude and duration of their exposure to asbestos

*from procedures that result in excised tissue; not all procedures do

Please Note

- The summary of the ITB in these slides is a condensed form of the information in the consent form and the ‘Participant Information’ document
- Please read the consent form and participant information sheet in full
    - the amount of information that Mount Sinai is legally required to include in the consent form is considerable – far more than your doctor has to give you when you go to him or her – because the ITB is considered research and has a consent form that can be used throughout North America, not just for one patient in one medical practice

Participation is Voluntary

- Participation is voluntary; the decision about whether or not to take part is totally up to you.
  - You can also agree to take part now and later change your mind. Whatever you decide is okay.
- Neither participating nor not participating in the ITB will affect your ability to get medical care.
- Any new information that develops during this research tissue bank which might make you change your mind about participating will be given to you promptly.

Who can participate?

- those exposed to asbestos from their work
  - do not need to be currently exposed to asbestos
  - IAHFIAW active and retired members
  - other asbestos-exposed workers
- those exposed to asbestos, but not from work
  - e.g. family of IAHFIAW members

Participating

- We will not be taking tissue from you just because you decided to participate!
- We hope we never get any tissue from you but, if, God forbid, you do develop an asbestos-related illness, and if that illness results in a diagnostic or treatment procedure that results in spare tissue, then we would like that tissue to not be thrown away and, instead, be sent to the ITB.

What’s Involved (if you decide to participate)

- If you ever go in for a <u>surgical procedure</u> for an <u>asbestos-related condition</u> we will need to know.
  - (surgical procedures: next slide)
  - asbestos-related conditions:
    - mesothelioma (both pleural [lungs] and peritoneal [gut])
    - lung cancer
    - pleural plaques
    - pleural thickening
    - pleural fibrosis
    - asbestosis

Surgical Procedures

- biopsy of the lung or pleura or gut
    - not liver biopsies and not skin biopsies
- CT-guided biopsy
- thoracoscopy
- VATS (Video-Assisted Thoracic Surgery)
- wedge resection (removal of a wedge of lung)
- lobectomy (removal of lobe of the lung)
- pneumonectomy (removal of the lung)

(if you participate, we'll give you a wallet card; you don't need to remember this list of procedures!)

If you *do* ever go in for a surgical procedure for an asbestos-related condition…

- we will need to know
- we will seek any <u>spare</u> tissue that is obtained during the normal course of some procedures, but which is not required for your routine care
  - not all procedures result in spare tissue
  - we will <u>not</u> be asking for any tissue to be obtained explicitly for the tissue bank, we ask only that you allow us to use your <u>spare</u> tissue
  - donating tissue to the ITB does <u>not</u> require you to undergo any extra diagnostic or treatment procedures, and does not change in any way how diagnostic or treatment procedures are done

If you *do* ever go in for a surgical procedure for an asbestos-related condition…

- In addition to the (solid) tissue you donate, we would like to get some blood, because some researchers are looking at what are called ‘markers’ - biological compounds that can be found in blood, rather than solid tissue
  - there are markers that are being investigated to determine whether they assess the degree of your exposure to asbestos
  - other markers are being investigated to determine whether they can provide an early indication of development of asbestos-related conditions

If you *do* ever go in for a surgical procedure for an asbestos-related condition…

- Routine before-surgery and after-surgery care sometimes require blood samples to be drawn.
    - If such samples yield spare blood, we will collect that.
    - If there is no spare blood from your routine pre-operative or post-operative blood draws, we would like to draw 6 teaspoons of blood for the ITB <u>while</u> they are drawing the pre- or post-operative blood
- We would like to do this each time you undergo surgery

If you *do* ever go in for a surgical procedure for an asbestos-related condition…

- your stored tissue will <u>not</u> be identified by your name or your social security number
  - instead, you will be assigned a unique ‘donor identification number’ which will be used to identify your samples
  - only Dr. Todd will be able to link any tissue samples you might donate back to your name

Information we receive with tissue

- your name
- sometimes the diagnosis
  - if you haven’t told us this and it isn’t included with your tissue sample, we will ask your doctor for this
- the ID number given to your tissue by the hospital that collected it
  - this information is not stored by the ITB
- sometimes, the medical record number given to you by the hospital that collected the tissue
  - this information is not stored by the ITB

Your Medical Records

- participating in the ITB does not result in your entire medical record being sent to the ITB, Mount Sinai or the IAHFIAW
  - we don’t need your entire medical record
    - if there’s a specific piece of information we need in the future, we’ll call you and ask you
  - (by the way, the doctor/hospital cannot send anyone your entire medical record without you signing a release explicitly stating to whom you want the records released)

No access to your identifiable information

- your tissue/blood samples that are used by researchers will not be identified by your name or SSN or any other means of personally identifying you
- researchers will not have access to your personal information that is in the ITB

Costs

- the ITB will not cost you anything
- the ITB will not cost your health insurance company (if you have one) anything
- (you will not receive any financial compensation for participating in the ITB)

Possible Benefits

- no one should expect donating tissue to benefit them directly right now; it’s a hope that new knowledge will help others in the future

What are the risks?

- Participating will not pose any risks to you from diagnostic or treatment procedures for any medical conditions you might develop in the future because participation does not require any additional procedures nor the alteration of any routine procedures.

Privacy

- researchers will not be able to identify you
- only ITB staff (me) will be able to identify you
  - I have to, to know that you're consented and to keep in contact with you
- We have a 'certificate of confidentiality' from the NIH. This provides another level of protection:
  - U.S. employers & insurance companies can't get your information
  - Canadian authorities have no jurisdiction over the (U.S.) ITB information
  - ITB information is not kept in Mount Sinai's medical record system

Tissue Donation Steps

- You or surgeon/MD will call me
- I send your consent to surgeon
- Surgeon collects tissue
- Pathologists test for diagnosis
- Once they’re done,
    - Pathologist releases unneeded tissue to ITB
    - Collecting hospital sends to Mount Sinai

Tissue Use

- Users will be clinicians and scientists in both academic institutions and drug companies
  - cancer, immunology, pathology, epidemiology, tumor biology, assay development
- The ITB will at all times maintain at least one aliquot of each fluid and tissue specimen obtained, for long-term archives
- Scientific Oversight Committee approves use
  - consists of IAHFIAW representatives and selected researchers

Feedback

- we propose to tell you of the advances made using your (collective, not individual) tissue
    - perhaps via the *Journal*
- ‘collective’ not ‘individual’ results because
    - tissue research requires tissue samples from many people before results are known;
    - interpreting the meaning for an individual of the latest new marker is dangerous if done prematurely
- BUT, if we find something important for you we *will* tell you if you want us to (consent form question 7)

Questions

- Feel free to ask all the questions you want before you decide

Andy Todd, Ph.D.
Mount Sinai
andy.todd@mssm.edu
212-824-7053 (office)
646-438-0597 (cell/after-hours)

If you would like to participate…

If you would like to participate

- first, thank you!
- second, you’ll need to complete a consent form

You only need to sign up once

- you only need to sign up once; you do not need to sign up every year
- once you're signed up, you can participate indefinitely
  - (or until you decide you no longer wish to participate)
- (we will need to re-consent you only if something major changes in the ITB's scope)
  - (there are no plans for any such major change)

Consent Form Instructions - 1 ‘Question’ pages (pages 6 & 7) [7&8 French]

- put your INITIALS next to the ‘yes’ or ‘no’ (*per* your preference) for each of the questions
  - 1 – 6 on page 6
    - if you say ‘no’ to question 1, you are electing to <u>not</u> participate in the tissue bank and therefore do not need to answer any of the other questions (you still need to sign and date the form though)
  - 7 – 10 on page 7

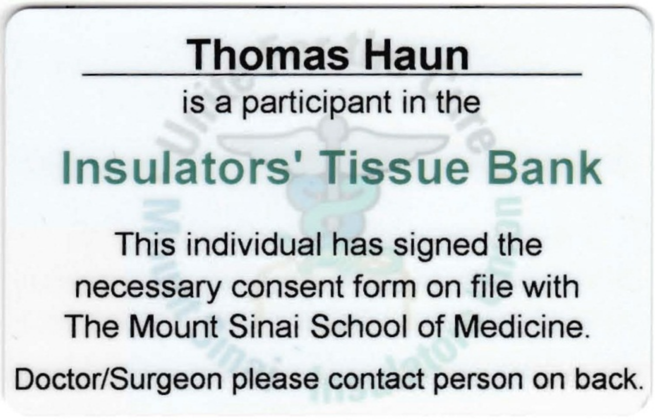
Consent Form Instructions - 1 ‘Signature’ page (page 15)

- Sign on the “Signature of subject” line at the top of page 15
  - do <u>not</u> sign on the ‘Person Explaining Study and Obtaining Consent’ line (that’s where Dr. Todd signs)
- Print your name below your signature
- Date the form, to the right of your signature

Consent Form Routing

- send the consent form to the International (FAO: Sheila Sonon)
    - Sheila generates the wallet card…
    - …and forwards the consent form to Dr. Todd, along with your contact information
- If he doesn’t consent you in person, Dr. Todd will call you once he receives your consent, to see if you have any questions and to ensure that you understand what you are consenting to
    - this is a legal requirement

If you enroll… / Helping you remember to let us know



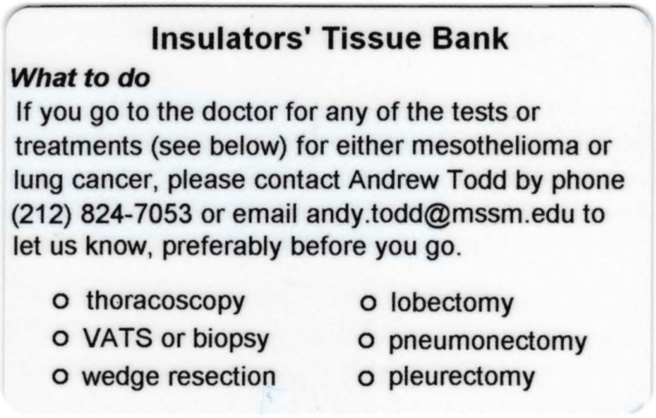
Thomas Haun

is a participant in the

Insulators' Tissue Bank

This individual has signed the
necessary consent form on file with
The Mount Sinai School of Medicine.

Doctor/Surgeon please contact person on back.



Insulators' Tissue Bank

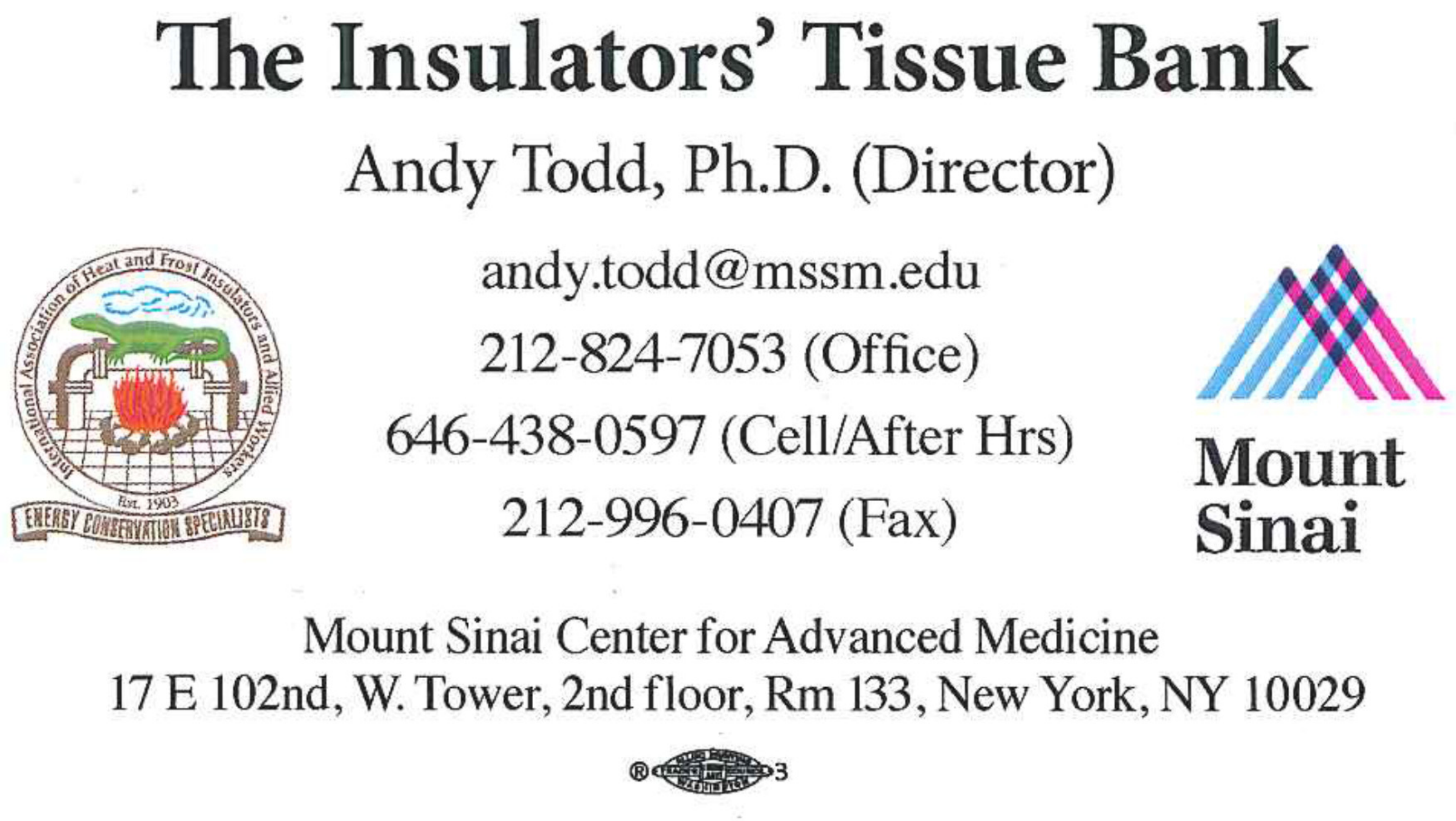
What to do

If you go to the doctor for any of the tests or treatments (see below) for either mesothelioma or lung cancer, please contact Andrew Todd by phone (212) 824-7053 or email andy.todd@mssm.edu to let us know, preferably before you go.

- thoracoscopy
- VATS or biopsy
- wedge resection
- lobectomy
- pneumonectomy
- pleurectomy

Consent Form Routing

- Once you’re consented, Dr. Todd can sign your consent form – at that point you are enrolled



The Insulators' Tissue Bank

Andy Todd, Ph.D. (Director)

International Association of Heat and Frost Insulators and Allied Workers
Est. 1903
ENERGY CONSERVATION SPECIALISTS

andy.todd@mssm.edu
212-824-7053 (Office)
646-438-0597 (Cell/After Hrs)
212-996-0407 (Fax)

Mount Sinai

Mount Sinai Center for Advanced Medicine
17 E 102nd, W. Tower, 2nd floor, Rm 133, New York, NY 10029

Thank You