Material Transfer Agreements for Human Samples: What They Are & When You Need One

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Introduction – Why are We Talking about MTAs?

- **High Volume**
  - FY16 figures for KUMC
    - 209 inbound MTAs, 67 outbound MTAs executed

- **Historic lack of clear policies** on when MTAs are needed
  - Especially in human subjects research context
  - “when in doubt, do one” is not feasible or desirable
  - ID scenarios with the most risk, and/or most IP to protect

- **KUIC / IRB collaboration to clarify policy & process**
  - Will be incorporated into new SOPs
  - Goal is to avoid delays in research start up
Roadmap

- **MTAs 101**
  - What is an MTA?
  - Common sections & issues
  - Provider’s responsibilities
- **Outbound Transfers of Human Samples (HS)**
  - Step 1: Can I send the HS?
  - Step 2: If yes to 1, do I *need* an MTA?
  - Step 3: If no to 2, do I *want* an MTA?
- **I need or want an MTA: where do I go?**
  - KUIC contact info & process
- **Q&A**

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Part I

MTAs 101
MTAs 101 – What is an MTA?

An MTA is...

An agreement documenting the transfer of materials, into or out of KU, for the recipient’s research purposes.

...transfer of materials...

- If any money (other than processing/handling/shipping fees for material) is being transferred, MTA is not appropriate
- Sponsored research, clinical trial, or service agreement can (and should!) cover material transfer if needed for project
- Can address data associated with the materials, but MTA is not appropriate for transfers of data sets alone (and not a substitute for a DUA if needed under HIPAA)
MTAs 101 – What is an MTA?

...into or out of KU...

- No MTA needed (or possible) for transfer of KUMC-created material from one KUMC faculty member to another
- No MTA needed (or possible) for transfer of KUMC-created material from KUMC to KU-Lawrence
- BUT...

MTAs 101 – What is an MTA?

...into or out of KU...

- If KUMC received the material under an MTA or other contract, double check whether the contract allows further transfer within KUMC/KU
- If KUMC collected the material under an informed consent form (ICF), make sure the ICF allows the transfer to Lawrence
  • more on this to come!
MTAs 101 – What is an MTA?

...for the recipient’s research purposes.

- KUMC sending material for its own purposes OR receiving material for provider’s purposes (in whole or in part) => subaward, sponsored research, collaboration, or service agreement is more appropriate
- MTA not needed for transfers related to clinical care
- Performing fee-for-service type of activity vs. research => service agreement is more appropriate

MTAs 101 – Common Sections & Issues

- Provider Scientist & Recipient Scientist
- Purpose of the exchange – what is recipient scientist doing?
  - The more complicated intellectual property terms are, the more detailed this should be
- Who can use the material?
  - Normally, only Recipient Scientist and those under his/her direct control & supervision – i.e., lab staff, grad students
- Provider retains ownership of the material – recipient has only limited license
- Intellectual Property (IP)
  - If Recipient Scientist invents something, who owns what?
MTAs 101 – Common Sections & Issues

- Publications – how recipient must acknowledge provider
- Biohazard issues
  - Provider lists any special shipping or storage instructions
  - Recipient promises to destroy safely when finished
  - Material not for use in humans
  - Provider disclaims liability for recipient’s (mis)use
- Termination date – how long can recipient use the materials?
- Processing & shipping costs, if any

MTAs 101 – Provider Responsibilities

- Provider should control legal terms
  - Some universities forgo MTAs altogether for basic, non-hazardous, non-proprietary materials (e.g., Stanford mice)
  - Provider generally supplies the initial MTA template
  - If provider tells you no MTA is needed, OK to follow BUT...
    - Think about whether you want one (or another type of contract) for your own purposes
    - Save the email to avoid future confusion, protect against provider policy changes, etc.
- Provider is responsible for making sure the material can be sent at all, and if so, leading on compliance issues
Part II
Outbound Transfers
of
Human Samples
(HS)

Outbound HS Transfers - Preface

- HS = tissue, blood, fluids, waste, and any cells or DNA extracted from these

- The following assumes that the HS being transferred out of KUMC was collected/created here
  - If it was received here from another institution (whether or not under an inbound MTA or other contract), STOP
  - critical first question is to see if provider’s IRB and/or contract permits the present transfer
  - KUIC will likely facilitate MTA from provider vs. do its own
Outbound HS Transfers - Preface

- **Primary Use** = HS is being transferred for the purposes of the protocol under which it was collected
  - Example: Clinical Trial XYZ, sponsored by AcmePharm, requires a blood draw to examine PK. Subjects’ blood samples are being sent to AcmePharm for AcmePharm’s PK analysis.
- **Future Use** = HS is being transferred for a purpose other than that of the protocol under which it was collected
  - Example: KUMC PI finished Clinical Trial XYZ about a year ago. Now she wants to send leftover blood samples to a colleague at Johns Hopkins looking for biomarkers.

Outbound HS Transfers – Step 1: Can I send HS?

**HRPP**
- How was the HS collected?
- What is recipient doing with it?
- What does the ICF say?
- HIPAA issues?

**Other**
- Does the CTA allow future uses?
- Is the material export controlled?
- Is it going to a foreign country or foreign national?

You need to clear both columns before proceeding.
Outbound HS Transfers – Step 1: Can I send HS?

HRPP Considerations

- Start by identifying the source of HS – how it was collected
  - Collected during clinical trial or other human subjects research (subject signed ICF)
  - Collected specifically for a repository (subject signed ICF)
  - Left over from analyses completed for clinical care (no ICF)

Outbound HS Transfers – Step 1: Can I send HS?

HRPP Considerations – clinical trial/other IRB-reviewed project

- If transfer is for primary use, ICF should include the following information for subjects:
  - Identity of the third-party recipient
  - How leftover HS will be handled
  - What info or identifiers will accompany the HS
  - Order from subject to KUMC to send HS to third party
  - Acknowledgment from subject that s/he won’t see results
  - If transfer is for genetic testing, acknowledgment from subject that third party can do testing, KUMC can store result
Outbound HS Transfers – Step 1: Can I send HS?

HRPP Considerations – clinical trial/other IRB-reviewed project
- If transfer is for future use, look at the ICF used to collect HS:
  - Does it contain a consent for future use of HS separate from the consent to participate in the trial, and did subject sign?
  - If so, what is the scope of the future use to which subject has consented?
    - OHRP: can’t request consent for “any future research” – there must be some relationship to primary use’s disease, drug, etc.
  - Does Recipient Scientist’s research fall within that scope?
- Reconsent subjects if no future use consent, or out of scope

Outbound HS Transfers – Step 1: Can I send HS?

HRPP Considerations – repository
- No “primary use” – everything is “future use”
- Analysis is similar to previous slide
  - How does the ICF define the scope of research for which HS can be used?
  - Does Recipient Scientist’s project fall within that scope?
    - Most common pitfall: for-profit companies wanting HS for commercial R&D (many ICFs limit use to non-commercial, academic purposes)
Outbound HS Transfers – Step 1: Can I send HS?

HRPP Considerations – clinical care leftovers
- The easiest was saved for last!
- No HRPP restrictions or considerations other than the following 2 “blanket” considerations

Outbound HS Transfers – Step 1: Can I send HS?

HRPP Considerations (regardless of source)
- HIPAA: what’s your strategy for compliance if HS is sent with information?
  - Send HS fully de-identified
  - Send HS with only “limited data set” PHI + execute a data use agreement
    - Contact KUMCRI ([ri-cda@kumc.edu](mailto:ri-cda@kumc.edu)) for DUA
  - ICF contains HIPAA authorization applicable to the recipient*
  - Reconsent subjects with a valid HIPAA authorization*
- *Even if HIPAA compliant, sending HS with identifiers may mean research needs recipient IRB’s approval under Common Rule
Outbound HS Transfers – Step 1: Can I send HS?

HRPP Considerations (regardless of source)
- **FDA**: is HS being used to establish the safety or effectiveness of an FDA-regulated device?
  - If so, FDA regulations apply on top of Common Rule
  - IRB of HS recipient may need to approve the use of HS
    - FDA defines “human subject” as “a human who participates in an investigation, either as an individual on whom or on whose specimen an investigational device is used or as a control”
    - **BUT** FDA provides exception for HS that are not “individually identifiable”, and other exceptions

Outbound HS Transfers – Step 1: Can I send HS?

HRPP Considerations (regardless of source)
For more detailed discussion and great hypos, see July 2011 guidance from HHS Office for Human Research Protections:

Outbound HS Transfers – Step 1: Can I send HS?

Other Possible Restrictions (1st of 2)

- CTA or other contract related to HS collection may limit future uses
  - HS may be sponsor’s “Confidential Information”
  - sponsor may own resulting HS, or at least any study drug within the HS

Outbound HS Transfers – Step 1: Can I send HS?

Other Possible Restrictions (2nd of 2)

- Export Control
  - Visit https://export-compliance.ku.edu/ for intro
  - In HS context, export control issues most often arise if sending anything involving a biological agent (e.g., virus) or anything biologically derived & modified to increase harm to humans or animals
  - If HS is export controlled AND going to 1) a foreign country or 2) a foreign national in US, need license or exception before you can transfer
Outbound HS Transfers – Step 2: Need MTA?

You’ve cleared the first hurdle to sending out HS: now what?

- “Yes” to any of these means an MTA is required
  - Need to protect IP or specify IP details?
  - Export control or other protection needed?
  - Need to restrict recipient to ICF’s future use scope?
  - Need to revoke HS if subject revokes future use consent?

*Note: Outcome of HIPAA and FDA analyses alone will not trigger MTA because MTA doesn’t affect compliance with these regulations. But either issue can be discussed in MTA if MTA needed for another reason.

Outbound HS Transfers – Step 2: Need MTA? – IP

- Unmodified HS – almost definitely no IP to protect
- Modified HS – possibly?
  - Assoc. for Molecular Pathology v. Myriad Genetics (2013 Supreme Court case)
    - “naturally occurring” DNA sequences are NOT patentable
    - “isolated” DNA molecules ARE patentable IF human intervention has created “markedly different” characteristics
  - Provide invention disclosure to KUIC before proceeding with MTA
Outbound HS Transfers – Step 2: Need MTA? – IP

- Are there “strings” attached to funding used to collect the HS?
  - Federal grant
    - Bayh-Dole Act may apply
    - KUMC has duty to ensure federal government’s non-exclusive license to inventions involving HS is maintained
  - CTA
    - CTA’s IP section may extend to all discoveries made with HS from the trial, especially if HS contains the study drug
    - Even if CTA allows the transfer for future use, MTA’s IP section may need to be modified to reflect CTA sponsor’s IP rights

Outbound HS Transfers – Step 2: Need MTA? – EC

- If Step 1 revealed that HS is export controlled, MTA can help...
  - prove qualification for an exception (fundamental research)
  - make customs process easier
  - document parties’ export control compliance procedure & duties

- If you know of any other regulation specific to your type of HS that recipient needs to follow, an MTA will require recipient’s compliance
Outbound HS Transfers – Step 2: Need MTA? – FU

- If Step 1 revealed that HS can be used only for certain types of projects permitted by “future use” section of ICF...
  - MTA’s specification of authorized use(s) ensures recipient can’t exceed scope of ICF
  - MTA’s specification that KUMC retains ownership of HS (and can demand return or destruction of HS) ensures KUMC can get HS back if subject ever revokes consent

Outbound HS Transfers – Step 2: Need MTA?

- If HS meets all of the following, **MTA IS NOT REQUIRED**
  - HS is collected as part of clinical trial/other IRB-reviewed research
  - HS is being transferred only* for primary use (i.e. same trial)
  - ICF contains all the elements described in Step 1 for this type of HS

*if primary use recipient wants to be able to keep leftover HS for its own future use later, do the “future use” analysis before sending!
Outbound HS Transfers – Step 3: Want MTA?

If you’re OK to send under Step 1 & KU won’t require an MTA under Step 2 – go forth and transfer your HS if you want!*

But also consider if any of the perks of MTAs are worth the time it takes to negotiate and execute (normally 1-2 weeks):

- Right to control use of HS and get it back if you want – good for “iffy” colleagues or rare specimens you don’t want wasted
- Right to require acknowledgment of you and/or your grant funding in publications – good for your rep & future applications
- Proof of promise to pay shipping or processing fees

*don’t forget to use EHS as a resource to make sure you’re shipping safely!

Part III
I Need or Want an MTA: Where Do I Go?
I Need or Want an MTA – Where do I go?

- KUIC handles all inbound & outbound MTAs for all KU campuses
  - General account: indcontracts@ku.edu
  - Laura Irick, J.D., Contract Specialist
    - 785.864.7403 / l.irick@ku.edu
  - Claire Koenig, J.D., Assistant Director, Industry Agreements
    - 913.588.5439 / claire.koenig@ku.edu
- KUIC sends a questionnaire for each MTA request to gather necessary details
  - If needed based on questionnaire answers, KUIC coordinates with IRB, EHS, Office of Export Control, or other offices to address any relevant compliance issues

Conclusion

- MTAs can be a useful tool for protecting IP and maintaining compliance when sending or receiving research materials
- For HS transfers, think ahead and carefully draft the ICF used to collect the HS to minimize risk and delay
- If you ever have questions about a transfer of HS, don’t hesitate to contact KUIC and/or IRB
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<thead>
<tr>
<th>Part IV</th>
<th>Q&amp;A</th>
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