SENDING DATA/SPECIMENS

Also applicable if data/specimens collected without consent and data/specimens to be shared with unaffiliated investigator

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This decision tree assumes that you already have IRB approval to collect or receive the data/ specimens .
See Receipt of Data/ Specimens if you do not yet have this approval.

START HERE
Does the consent under which the specimens /data were collected already give consent for this sharing?

Yes → Obtain a Non Funded Agreement (NFA) with Grants & Contracts office. Provide G&C office with Protocol IRB #

NA or No → If the data/ specimens were collected under a research consent form, does the consent PROHIBIT the use of data/specimens as outlined in this project?

Yes → Data/ specimens may NOT be sent!!

NA or No → Will data be sent to an NIH Designated Data Repository by UVa?

Yes → Will UVa receive grant funding from a non common rule agency (e.g. Dept of Justice) for this protocol?

Yes → If not done already, submit IRB Grant Application to IRB-HSR. The Grant Information Form will supply the IRB-HSR office with information needed to process the Institutional Certification to deposit data into an NIH Designated Database.

No → Will you be sending data/specimens that meet the criteria of "Identifiable" under HIPAA regulations?

Yes → Study team must track disclosure in
Check HIPAA tracking on reg page
Note disclosure in comment field/assurance form

No → Submit a "Genomic Data Sharing Submission Certification Request Form" to the IRB.

No → Will you be sending data/specimens that are coded and the key to the identity of the subject will be kept at UVa?
Data also meets the criteria of a LDS under HIPAA regulations.

Yes → Do all of the following criteria apply?
- Data/specimen, in its entirety, were collected for this project.
- You will be collaborating * with the outside researchers on this project.
- You do not have funding for the work being done by person receiving data/ specimens.

No → Obtain a NFA from G&C Office.
Not Human Subject Research-Project team submits Determination of Human Subject Research form to IRB-HSR.
Subject signs HIPAA Authorization OR Privacy Board grants waiver of HIPAA Authorization and tracking of disclosure required in EPIC.

Yes →
- If data/specimens were collected under UVa protocol- modify the protocol .
  Provide IRB# to SOM Office of Grants and Contracts.
- If data/specimens were NOT collected under a UVa protocol- Go to Protocol Builder- Answer YES to Non-engaged

For both do all the following:
- Obtain a Non Funded Agreement (NFA) with SOM Office of Grants & Contracts . NFA to include a HIPAA DUA if data/specimens are Coded.
- IS Decision Support Office researchdata@hscmail.mcc.Virginia.edu to review datasets prior to NFA being signed to confirm data meets the criteria of a LDS if Coded.

WARNING- TRACKING WILL BE REQUIRED IF DATA/ SPECIMENS ARE IDENTIFIABLE PER HIPAA REGULATIONS

No → Do all of the following criteria apply?
- Data/specimen, in its entirety, were collected for purposes other than the project to be done by those with whom you are sharing data/specimens
- You will not be collaborating * with the outside researchers on their project.
- You do not have funding for the work being done by person receiving data/ specimens.

Yes →
- Obtain a Non-Funded Agreement (NFA) with SOM Office of Grants and Contracts. NFA to include a HIPAA DUA.
- IS Decision Support Office researchdata@hscmail.mcc.Virginia.edu to review datasets prior to NFA being signed to confirm data meets the criteria of a LDS.
- OPTIONAL: submit a Determination of Human Subjects Research Form to IRB: *NOT Research*

No → Will you be sending data/specimens outside of UVa that meet the HIPAA criteria of de-identified?

Yes →
- Obtain a Non- funded Agreement (NFA) with SOM Office of Grants & Contracts
- IS Decision Support Office researchdata@hscmail.mcc.Virginia.edu to review datasets prior to NFA being signed to confirm data meets the criteria of de-identified.
- OPTIONAL: submit a Determination of Human Subjects Research Form to IRB: *NOT Human Subject*

***Collaborating may be done in several different ways.**
You would be considered to be collaborating if any of the following occur:
- You will receive data back from those to whom it was originally sent.
- You will assist in writing the paper/abstract

Any item noted in Blue found on IRB-HSR website under FORMS