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

RECEIPT OF DATA/SPECIMENS

Version Date : May 1, 2019

START HERE: MUST READ!!
Contact IRB-HSR Director if PI is new to UVa and bringing samples/ data with them from previous institution.
***If data/specimens were collected under a research consent, the consent must NOT prohibit the use of data/ specimens as outlined in this project .*
Will you be receiving de-identified data/specimens?
ANSWER NO IF:
- Research falls under the authority of the FDA **OR**
- Data/specimens will be coded and the supplier will retain the key to the code.
- The study involves the use of viable human embryos, human fetal tissue, human embryonic stem cells (HESC), induced pluripotent stem cells (IPSC) or human embryonic cell lines?

ANSWER YES if no code / no key to code exists AND none of the criteria below apply:
1. If receiving data from dbGaP, you submitted some of the data to dbGaP and you hold the key to identifiers, answer questions as if data is identifiable. (Answer this question NO)
2. If receiving data from dbGaP & you will collaborate with those who submitted the data and they hold the key to identifiers, answer questions as if data is identifiable. (Answer this question NO.)

Yes

Does the submission meet the criteria for non human subject research?
HINT: Review the Determination of Human Subject Research form.

Yes

Complete
Determination of Human Subject Research
If receiving data from dbGaP: this form is required if IRB approval is required by DUC, otherwise optional. Also contact Grants and Contracts office for NFA and Data Request Form/ Institutional Certification.
On ePRF:
No to Human Subjects Research,
NA to Exempt

No

Will data from the study be submitted to the FDA?

Yes

Submit:
- **IRB Application for Expedited or Full Board Review OR**
- Request for IRB Reliance Agreement
- (External IRB/Ethics board MUST have an FWA)
  (*Full Board review required if giving results back to subjects.*)
- Genomic Data Sharing Submission Certification Request Form if receiving data from dbGaP
- **On ePRF answer:**
- YES to Human Subjects Research
- NO to Exempt

***NOTE: You will also have to submit Grant Proposal to IRB for review and approval if the protocol has outside funding from a non common rule agency (e.g. Dept of Justice) .*
For Grant Submission Process see IRB-HSR Website at http://www.virginia.edu/vpr/irb/hsr/submit_grant.html

No

Will the study involves the use of viable human embryos, human fetal tissue, human embryonic stem cells (HESC), induced pluripotent stem cells (IPSC) or human embryonic cell lines?
(If yes, review by full board required)

Yes

No

Will you be receiving coded data/specimens?
Answer NO if you hold the key to code OR item 1 or 2 to left apply.
Answer NO if there is a code, but the group sharing data with you does not hold key to code (key to code held by a 3rd party).
Answer YES if a key to the code exists and it will not be shared with you. You will not receive any HIPAA identifiers.

No

Will data/specimens meet the criteria of De-identified, Limited Data Set per HIPAA OR review of medical records and collecting identifiable data protected by HIPAA?

Yes

Submit: EXEMPT APPLICATION
On ePRF answer:
Yes to Human Subjects
Yes to Exempt

Yes

Were the data/ specimens originally collected for this research?

Yes

DHHS/ OHRP states either the supplier or receiver is involved in human subject research- therefore you must submit IRB approval from supplier.
Submit:
- **NON-ENGAGED APPLICATION** to IRB
- IRB approval from group that obtained data/specimens from subject.

On ePRF answer:
- YES to Human Subjects Research
- NO to Exempt

NOTE: You will NOT have to submit Grant Proposal to IRB for review and approval.

No

Will you and those supplying the coded data/specimens be working on the same project?
(e.g. all parties will be listed on the paper/ will give data back to supplier?)

No

Submit:
Human Subject Research Determination Form & submit Genomic Data Sharing Submission Certification Request Form to IRB-HSR if receiving data from dbGaP
On ePRF answer:
- NO to Human Subjects
- NA to Exempt

NOTE: You will NOT have to submit Grant Proposal to IRB for review and approval.

Yes

Will data/specimens meet the criteria of De-identified or Limited Data Set per HIPAA?**
NOTE: Supplier may retain a key to the code.

**Only HIPAA identifiers: dates / address- zip code or bigger.

No

Will UVa receive funding directly from DHHS to conduct this study?
Non-engaged criteria only applies if no direct funding from DHHS. LDS allowed under non-engaged

Yes

Submit: EXEMPT APPLICATION
On ePRF answer:
Yes to Human Subjects
Yes to Exempt