RUTGERS
THE STATE UNIVERSITY OF NEW JERSEY

SOP: GDPR Review Procedures

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1. PURPOSE

1.1 This procedure establishes the process for the IRB to approval Human Research Studies which are governed under *General Data Protection Regulation (EU GDPR)* regulations.

1.2 The process begins when an IRB reviewer identifies a Human Research Study which could potentially be governed under GDPR.

1.3 The process ends when the Human Research Study is confirmed not to be governed under GDPR or the Rutgers IRB receives *Rutgers University Ethics and Compliance* confirmation that the study is compliant with GDPR and the IRB Office approves the study.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None.

3 POLICY

3.1 The IRB may only approve GDPR studies which are confirmed to be compliant to GDPR by Rutgers University Ethics and Compliance (UEC).

4 ROLES

4.1 IRB Office (Rutgers Human Subjects Protection Program)
4.2 IRB eIRB Reviewer (Rutgers Human Subjects Protection Program)
4.3 UEC GDPR Reviewer (Rutgers University Ethics and Compliance)
4.4 Rutgers Principal Investigator (Rutgers University)

5 RESPONSIBILITIES

5.1 The Rutgers IRB must identify any study submitted to the IRB office including initial submissions, modifications, and continuing reviews for applicability to GDPR.

5.2 Rutgers UEC confirms study is compliant with GPDR regulations, if applicable.

5.3 For situations when Rutgers University is relying on another IRB for IRB Approval, GDPR compliance is the responsibility of both institutions (GDPR Controllers and Processors).

6 PROCEDURE

6.1 Rutgers IRB Reviewer reviews study submission to flag any potential GDPR related activities.
- 6.1.1 Common areas reviewed in eIRB include:
  - 6.1.1.1 Research Protocol
  - 6.1.1.2 eIRB Short Title (For International References)
  - 6.1.1.3 eIRB Section 5.1 > 3.0 For Non-Rutgers International Sites
  - 6.1.1.4 eIRB Section 5.1 > 4.0 For Appendix C (International Research)

6.2 If any confirmed or suspected activities governed under GDPR are found, the Rutgers IRB Reviewer completes HRP-335 – WORKSHEET – GDPR for study in question.

6.3 Based on HRP-335 results, if GDPR is found to be applicable to the study, the GDPR Review process may continue.

6.4 IRB Reviewer notifies Principal Investigator of GDPR requirements and how they may apply to their study.

6.5 IRB Reviewer will provide alternatives to avoid GDPR review if PI wants to remove GDPR activities.

6.6 IRB Reviewer will refer Researcher to review IRB GDPR guidance webpage to ensure all IRB GDPR requirements have been added to the study.

6.7 IRB Reviewer will confirm that Researcher wants to continue all GDPR study activities.

6.8 IRB Reviewer will complete initial IRB review of study for IRB Human Subject Protection purposes.

6.9 IRB Office will coordinate Rutgers UEC's concurrence for GDPR Approval and notify Rutgers UEC via email and request GDPR review in eIRB.

6.10 If both the IRB Reviewer provides approval for the study and Rutgers UEC provides approval concurrence for the study, an IRB approval letter can be created by the IRB Office when IRB Reviewer approves the study in eIRB.

7 MATERIALS

7.1 HRP-335 – WORKSHEET – GDPR

7.2 IRB GDPR guidance webpage

8 REFERENCES

8.1 21 CFR §56.111 Criteria for IRB-Approval of Research (FDA)

8.2 45 CFR §46.111 Criteria for IRB-Approval of Research (OHRP)

8.3 GDPR Regulations: https://gdpr-info.eu/