Documents needed to process data requests within IDR

An IDR analyst can provide data for a specific study only after an IRB protocol has been approved. Sections below provide information what documents should be provided to IDR in order to process a request for data. Please see cohort discovery and consultation pages to see how IDR can help before an IRB is approved.

wcg IRB/WIRB

If a study team is submitting a data request to fulfill requirements for a study approved by a wcg IRB/WIRB, the study team needs to provide the following documents to IDR:

1. wcg/WIRB protocol.
2. Certificate of Action. It should be the latest one, which shows that the approval has not expired.
3. One of the following documents depending on the step that IDR will be helping with:
    a. HIPAA Waiver of Authorization if IDR will help to identify patients that meet the inclusion criteria.
    b. Blank consent form that a recruited patient would sign if IDR will help by providing data for already recruited patients. We need to see that the patient agrees to share specific data that is requested by the research team.

sIRB/CEDE IRB

If a study team is submitting a data request to fulfill requirements for a study approved by an sIRB/CEDE IRB, the study team needs to provide the following documents to IDR:

1. pdf of smart IRB protocol submitted through myirb.ufl.edu.
2. pdf of Letter of Approval by UF IRB. It should be the latest one, which shows that the approval has not expired.
3. Protocol that was uploaded in Protocol Document subsection of Study Overview section in smart IRB.
4. Blank consent form that a recruited patient would sign if IDR will help by providing data for already recruited patients. We need to see that the patient agrees to share specific data that is requested by the research team.

UF IRB

If a study team is submitting a data request to fulfill requirements for a study approved by UF IRB, the study team needs to provide the following documents to IDR:

1. pdf of smart IRB protocol submitted through myirb.ufl.edu.
2. pdf of Letter of Approval by UF IRB. It should be the latest one, which shows that the approval has not expired.
3. Protocol that was uploaded in Protocol Document subsection of Study Overview section in smart IRB (if protocol was uploaded).
4. Blank consent form that a recruited patient would sign if IDR will help by providing data for already recruited patients for studies approved under “Direct authorization through consent form” selection in “HIPAA Authorization Determination”. We need to see that the patient agrees to hare specific data that is requested by the research team.
5. Data collection sheet if a separate file was uploaded in Data Collection section of smart IRB.