*Compliance Documentation Checklist

(For BOTH externally and internally funded clinical research)

PI Name: Click here to enter	**Status of this compliance package submission:** ☐ New (initial compliance package submission) ☐ Revised (amendment of initial package)
PI Department: Click here to enter	
PT/PD/SC #: Click here to enter	
HM #: Click here to enter	**Clinical Trial Registration (NCT #):** Click here to enter

Protocol Type *(select one)*:

- ☐ Clinical Trial
- ☐ Clinical Research *with* no *clinical trial component*
- ☐ Clinical Research *with a clinical trial component* (*select one*): ☐ scheduled to begin at initiation of the award ☐ proposed for later in the project

Initiator *(select one)*:

- ☐ Investigator-Initiated Protocol: Enter Version Date/Reference #
- ☐ Sponsor-Initiated Protocol: Enter Sponsor Protocol #

Resource Types *(select all that apply)*:

External
- ☐ Financial Resources: e.g., NIH; NIDDK, Pfizer, other
- ☐ Executed Materials Transfer Agreement (see requirements): Identify party with which agreement has been executed

Internal
- ☐ Financial Resources: Specify school/center-required information

Document Checklist:

ALL: ☒ This Checklist

- ☐ Budgeting and Billing Compliance Package:
  - ☐ Prepared Internal Budget (Sample; Tips)
  - ☐ *All applicable* Ancillary Pricing Quotes
  - ☐ *The required* Clinical Research Cost Analysis Form for
    - ☐ *Non-Clinical Trial* *or* ☐ *Non-Device CT* *or* ☐ *Device CT*
  - ☐ Prepared Billing Grid
  - ☐ Prepared Billing Set-Up Form (including NCT#)
  - ☐ Prepared **Enrollment Log (including NCT#)
- ☐ Protocol/Synopsis or Proposal Submission
- ☐ Informed Consent Document Draft
- ☐ Other: Specify additional documents (e.g., MTA).

ADDITIONAL (if supported by External Financial Resources):

- ☐ VCU Internal Approval Form (IAF) -- *placed behind this form*
- ☐ External/Sponsor's Budget, if provided -- *placed behind internal budget*
- ☐ Contract if provided by Sponsor (Industry/other)
- ☐ Other: Note any additions/exclusions, such as sponsor-required forms.

Notes:

Click here to enter text.

Budgeting / Billing Responsibilities:

Budget developed by: ☐ CCTR Clinical Research Services ☐ SOM Central ☐ MCC Central ☐ Other: Click here to enter text.

Initial billing documents to be submitted to VCUHS by: ☐ School/Center (Internal-Funding) ☐ OSP (External Funding)

External sponsors to be billed by: ☐ Research Team ☐ Department Administration ☐ Grants and Contracts

Clinical Service Providers:

☐ VCUHS/MCVP ☐ VCU Dentistry ☐ Other: Click here to enter text.

OnCore:

Study entered into OnCore by: ☐ SOM ☐ MCC ☐ CRS

Compliance Document Package Verified By:

Name: First and Last Name Email Address: Email Address

*See second page for definitions/instructions **Inclusion of the enrollment log is recommended, but not required at this time.

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(For BOTH externally and internally funded clinical research)

Purpose	To facilitate and record school/center receipt and review of key compliance documents supporting clinical research, applying these standards uniformly to both internally-supported and externally-sponsored/proposed clinical research.
Preparation & Submission	The school/center should define who utilizes this checklist to document final 'clinical research package preparation' prior to school/center review. The submission workflow: • **SOM** preparers submit this checklist to SOM Office of Research Administration (in accordance with their requirements). • **MCC** preparers submit this checklist to the MCC Office of Research Administration (in accordance with their requirements). • **All other schools** submit this checklist to the CCTR Clinical Research Services Office (with complete clinical research package).
Definitions and Resources (by checklist section)	
Heading	• **Identifiers:** PI Name and Department should match other documents, no format requirement. • **Status:** Differentiates between initial and revised/amended submissions. • **PT/PD/SC #:** *(If available)* - A unique number assigned by the Office of Sponsored Programs database. • **HM #:** *(If available)* - A unique number assigned by the VCUIRB database. Resources: IRB/Human Research Protections • **Clinical Trial Registration NCT#:** VCU Clinical Trial Registration Policy, clinicaltrials.gov Account Create Form
Protocol Type	• **Clinical Trial:** An interventional or observational prospective research study involving human subjects that is designed to answer specific questions about biomedical (e.g., drugs, treatments, devices) or behavioral interventions (e.g., diet modifications, physical activity) through the compliant collection and analysis of safety and efficacy data as measurement for health outcomes. In an interventional clinical trial, research subjects are assigned to a treatment or other intervention and their outcomes are measured. In an observational clinical trial, interventions given during the course of clinical care are observed and outcomes are measured by the researchers. Preclinical laboratory studies or studies in animals are not considered clinical trials. • **Clinical Research with no trial component:** Patient-oriented research conducted on material of human origin (tissue, specimens, and cognitive phenomena). If checked, the protocol should not otherwise meet the definition of clinical trial. The research may include epidemiological and behavioral studies, outcomes research, and health services research. • **Clinical Research with a clinical trial component:** If checked, the protocol should meet the definition of clinical research, but have a future clinical trial component. Indicate if the clinical trial component is scheduled to begin (a) at the time the award is made or (b) at a later time during the project.
Initiator	• **Investigator-Initiated Protocol:** When the principle investigator has initiated or designed/authored the research protocol independently or collaboratively. • **Sponsor-Initiated Protocol:** When the intended sponsor initiated or designed/authored the research.
Resource Types	• **External:** Note origin of financial resources. If materials are provided outside of the scope of a Clinical Trial Agreement, a Materials Transfer Agreement must be negotiated between VCU Innovation Gateway and the provider of materials. • **Internal:** Identify financial resources committed, as specified by the school/center requirements (e.g., departmental funds, pool accounts, internal research awards, account detail).
Document Checklist	**All:** (Necessary documents for internally-supported *and* externally-supported/proposed research): • **Budgeting and billing** compliance package guidance and forms: Clinical Trial Budgeting Best Practices; Sample Internal Budget - Template, Ancillary Pricing Structure and Process; Cost Coverage Analysis Process (Clinical Research Cost Analysis Forms, Billing Grid, VCU Billing Set-Up Form, Enrollment Log (recommended, to ensure preparation with correct NCT#). **Protocol/Synopsis or Proposal Submission:** Recommended format for a human research protocol (World Health Organization); Proposal Writing Resources (compiled by VCU Research Development), PI Proposal Checklist (via OSP). • **Informed Consent Draft:** Best practice is to include the draft of the informed consent document submitted for IRB review for research which could be activated promptly following school/center processes (when internally-sponsored) or VCU OSP processes (when externally-sponsored, e.g., industry contract). For more informed consent drafts/requirements, see: VCU Institutional Review Board. • **Other:** This space is provided as an option to document additional requirements (e.g., controlled substances). **ADDITIONAL:** (These documents are necessary ONLY FOR externally-supported/proposed research): • **IAF:** VCU Internal Approval Form (IAF), IAF Instructions (IAF) • **External Budget:** As applicable, budget in sponsor-required format or on sponsor required forms. The final budget figures/plan must match the internal budget (VCU format). • **Contract:** If applicable, written agreement between the Institution (VCU) and the sponsor (typically applies to industry-sponsors).
Budgeting & Billing	Identify the groups responsible for budget development, VCUHS initial billing document submission, and billing of any external sponsors.
Clinical Service Providers	Identify groups within VCU responsible for providing clinical services. Please note VCUHS Policy 4PC.CP.004 (v1) Conduct of Clinical Research In Patient Care Areas.
OnCore	Identify the group that entered basic data into OnCore for this clinical research protocol. *NOTE:* The CRS is currently the data-entry point for all non-SOM and non-MCC studies.
Verification	Identify the individual verified completion of the compliance documentation checklist/package (include email).