University of Virginia School of Medicine Standard Operating Procedure for new faculty who will perform clinical research
Latest modifications: updated links to the new Clinical Research site ver. July 2017

Topic/requirement	Task to be completed/observations	Contacts and responsible parties	Lead time required
Make contact before leaving your current institution (important meetings)			
Contact your UVA department administrator	It is important to understand your UVA department's administrative structure and the services they provide to faculty.	Your UVA administrator will describe this organization and introduce you to the appropriate members of his/her staff.	Make contact before leaving for UVA.
Contact SOM research offices	Familiarize yourself with SOM and UVA procedures for finding, proposing, and administering externally-funded projects by contacting these offices/individuals.	▪ SOM Office of Grants and Contracts/Stewart Craig – policies and procedures. ▪ SOM Office for Research/Steven Wasserman – grant opportunities, finding collaborators, managing the science.	
Grants, contracts, and consulting agreements			
Transferring external research awards to UVA	Obtain approval from the funding agency and your existing institution for the transfer. Not all awards can be transferred between institutions.	Your current and UVA administrators, in collaboration with their respective grants offices and the funding agency.	Varies
Transferring consulting agreements to UVA	School of Medicine policy requires that consulting agreements be reviewed institutionally before they are signed.	Contact your UVA administrator, who will work with the SOM Office of Grants and Contracts to generate such agreements.	Varies
Identifying research funding sources	Identify internal and external funding sources to support your research program.	Check the Office for Research web site on finding and applying for funding. Subscribe to *From the Dean's Office*. Search for funding opportunities in *Pivot* or *GrantForward*.	Varies
Preparing budgets for clinical trials; invoicing for costs	Precise budgets and knowledge of standard of care, to apportion charges, are critical elements of generating a budget.	The SOM Clinical Research Office assists investigators in preparing clinical trials budgets, negotiates with the prospective sponsor, and will invoice the sponsor as study milestones are achieved.	
Applying for external funding before your arrival	You can submit proposals for research funding through UVA prior to your arrival, with departmental approval.	Your UVA research administrator can prepare and route the grant. S/he will forward it to the SOM Office of Grants and Contracts, which reviews, approves, and submits (if appropriate) the proposal.	Administrative sections due at OGC 5 working days before deadline; scientific sections due two days prior to deadline.

University of Virginia School of Medicine Standard Operating Procedure for new faculty who will perform clinical research
Latest modifications: updated links to the new Clinical Research site ver. July 2017

Topic/requirement	Task to be completed/observations	Contacts and responsible parties	Lead time required
Applying for funding while at UVA	Develop your proposal and obtain a review by your colleagues; obtain institutional approval; submit the proposal to the funding agency.	▪ Your Chair/Director may require (and we strongly recommend) an internal review of your proposal. ▪ Your UVA administrator can generate budgets and application forms and forward the proposal to the SOM Office of Grants and Contracts (OGC) for review and approval.	Administrative sections due at OGC 5 working days before deadline; scientific sections due two days prior to deadline.
Consulting activities at UVA	SOM policy requires that consulting agreements be reviewed by the Office of Grants and Contracts prior to approval.	Contact your UVA administrator, who will work with the SOM Office of Grants and Contracts to generate such agreements. (Consulting policy.)	Varies
Personnel (staff and trainees)			
Transferring staff to UVA	Create staff positions within the UVA HR system; interview and select candidates.	Department/Center HR administrator, with SOM and UVA HR offices.	Several weeks
Hiring staff	Create positions within the UVA HR system; interview and select candidates.	Department/Center HR administrator, with SOM and UVA HR offices.	Varies
Trainees (graduate students and postdocs):			
Joining a UVA graduate program	Members of the Biomedical Sciences Graduate Programs (BIMS) have access to students for their research.	To join a BIMS program, contact Amy Bouton, Associate Dean, Graduate and Medical Scientist Programs	
Financial and other support for graduate students	SOM covers year 1 of grad student stipends; thereafter, they are supported financially by departmental or grant funds. Information sources for enrolled graduate students.	Graduate program directors and the Graduate Programs Office/Dr. Janet Cross: ▪ BIMS student application site ▪ Information for enrolled students	
Other visitors to your group	Obtain clearance for visitors in UVA facilities.	SOM volunteer forms can be found at https://med.virginia.edu/office-for-research/resources-and-collaborators/forms-and-documents/.	1 week
Visas	Obtain and maintain required US visas for international scholars. UVA visa support is described at www.virginia.edu/iso/issp/.	Your UVA administrator will work with SOM, UVA International Studies Office (scholars) or UVA HR (employees), and the Dept. of State to process visas.	Varies substantially
Training for UVA supervisors	All supervisors must take mandatory training on Discrimination and Harassment.	Your administrator will arrange such training with the Office of Equal Opportunity Programs.	

University of Virginia School of Medicine Standard Operating Procedure for new faculty who will perform clinical research
Latest modifications: updated links to the new Clinical Research site ver. July 2017

Research supplies, equipment, travel			
Transferring equipment and supplies from your current institution	Transfer depends upon your current institution's policies: equipment purchased using institutional funds may not be transferable. If permitted, identify a UVA contract mover to perform the physical transfer and provide special handling.	Your current research administrator and institutional administration can determine what you may transfer and can arrange the move of such items.	Several weeks
Ordering supplies, equipment, and services	These items are ordered through your department, using either your start-up funds or other sources of support.	Your UVA administrator can arrange for a member of your staff to obtain training in UVA Marketplace, an on-line shopping system. Your administrator can facilitate the purchase of equipment and services.	Varies
Travel	Arrange, document, and get reimbursed for the cost of job-related travel.	Your UVA administrator can help with all aspects of travel. Procurement Services' guidelines and tips on travel can be found at http://www.procurement.virginia.edu/forms/TravelGuidesKnowBeforeYouGoAll.pdf.	Varies
Track the financial status of your accounts	Monthly review and approval of your accounts, as required by UVA.	Your UVA administrator will provide you with monthly reports of expenditures on each of your internal accounts, as recorded in the Oracle financial system. You should review and sign off on the accuracy of these reports.	
Human subjects research			
All things clinical	Most everything you wanted to know about conducting clinical trials in a single web site.	Access the SOM Clinical Research Office site at: http://research.med.virginia.edu/clinicalresearch/research-resources/offices-supporting-clinical-research/clinical-research-unit/.	
Development of human use protocols and case report forms (CRFs)	Avoid pitfalls when developing an investigator-initiated protocol.	▪ The SOM Clinical Research Office can help investigators prepare protocols and CRFs. ▪ Division of Biostatistics & Epidemiology (Dept. of Public Health Sciences) can help with designing studies, developing analytic plans, and analyzing pilot data.	
Development of INDs/IDEs for submission to the FDA	Investigational New Drug Applications and Investigational Device Exemptions are required for all clinical trials of new drugs and devices, respectively	▪ The SOM Clinical Research Office can help investigators prepare these documents. ▪ The Investigational Drug Service also can help with the IND preparation process.	

University of Virginia School of Medicine Standard Operating Procedure for new faculty who will perform clinical research
Latest modifications: updated links to the new Clinical Research site ver. July 2017

Submitting human use protocols to the IRB	Take on-line IRB training (log on as a guest) to allow you to submit protocols and exemption requests to the committee. Submit protocols or requests for IRB exemptions as early as possible.	The IRB for Health Sciences Research (IRB-HSR) Web provides on-line training and protocol submission.	Weeks to months for final approval or exemption
Training for clinical research coordinators (CRCs)	Initial training and continuing education of clinical study personnel is required to maintain Good Clinical Practice.	▪ The IRB-HSR requires on-line training for clinical coordinators and a voluntary program on IRB and broader clinical studies issues. ▪ The SOM Clinical Research Office conducts continuing education, informal discussions, clinical research professionals' meetings, and mentoring to individual CRCs.	
Recruiting research subjects		▪ UVA Health System (HS) Web site lists current clinical trials (request to list your trial). ▪ The IRB-HSR Web site provides guidelines for advertising for study participants, including templates for local media outlets.	
Phlebotomy services	Fee-for-service blood drawing.	Contact the Clinical Research Unit (http://research.med.virginia.edu/clinicalresearch/research-resources/offices-supporting-clinical-research/clinical-research-unit/contacts/). Investigators who perform phlebotomy in non-patient care areas must register with the Institutional Biosafety Committee.	
Specimen processing services	Fee-for-service specimen processing outside the Medical Center Clinical Laboratory.	The Biorepository and Tissue Research Facility (BTRF) processes specimens on a fee-for-service basis. Investigators must transport specimens to the BTRF. Contact Craig Rumpel (982-6453) to discuss costs and to arrange access to this service. Investigators processing and shipping their own specimens must register with and receive training from the Institutional Biosafety Committee.	
Pharmacy services	Receipt, logging, preparation, blinding of study drugs.	The Investigational Drug Service can provide all of these functions.	
Coordinators and clinical space for investigator-initiated research	Use of a central facility for the conduct of in- or outpatient studies.	See this site for information on inpatient and outpatient facilities, staff, core laboratory assays, and computing and statistical support.	

Quality assurance and monitoring activities	QA includes preparation and maintenance of SOPs, and preparing for sponsor/FDA audits. Study monitors are required for investigator-initiated studies.	The SOM Clinical Research Office can help investigators with both of these functions.	
Publicly register your clinical trials	Federally-sponsored clinical studies must be registered on the Web; industry-sponsored trials should, as well. The sponsor is responsible for registration.	See http://www.clinicaltrials.gov/. Register your trial at http://prsinfo.clinicaltrials.gov/.	
Conducting retrospective research using hospital patient data	Such studies might include outcomes analyses, policy studies, or generating preliminary data for proposals.	The Clinical Data Repository clinical information for the retrospective analysis of health care data.	
Research data			
Transferring research data to UVA	Obtain approval to transfer data before you leave. Often, originals must remain at your old institution, but you can take copies. *Do not* transfer information covered by confidentiality agreements before they are in place at UVA. Any data including patient/subject identifiers are covered by HIPAA.	- Your current administrator and VP for Research can approve data transfers. - Your technology office can help obtain approval to transfer confidential information (see above). - Your current IRB can advise on transfers of clinical data.	Varies
Intellectual property, confidentiality			
Transferring proprietary materials to UVA:			
Materials developed at your current institution	Obtain permission from your current institution to transfer such materials (e.g., drugs, novel reagents, clinical specimens). Permission may be denied if your institution has licensed the materials with restrictions on future use.	Your current technology office and your UVA administrator, in collaboration with the UVA Office of Grants and Contracts.	Varies
Materials obtained under MTA	For materials obtained from other institutions or companies, you should request their use at UVA *de novo*, rather than obtaining permission through your current institution.	Your UVA administrator will coordinate the laboratory or company providing the proprietary materials and the SOM Office of Grants and Contracts.	Varies
Transferring confidentiality agreements (CDAs) and confidential information	Request that new CDAs be generated between UVA and the company that had provided the original agreement.	Your current technology office will work with your UVA administrator and the SOM Office of Grants and Contracts to identify existing agreements and the other entities involved.	Varies

Inventions and other intellectual property (IP)	Protect your IP using patents, confidentiality agreements (CDAs), and materials transfer agreements (MTAs).	▪ Your UVA administrator can help you submit invention disclosure forms. ▪ The UVA Patent Foundation can advise on disclosure, patenting, and licensing. ▪ Your UVA administrator can work the Office of Grants and Contracts to finalize CDAs and MTAs.	Varies
Research facilities			
Renovating your research space	Initiate the renovations process prior to arriving at UVA, since its duration depends on the project scope, number of design changes, and budgetary limits.	Your UVA research administrator will be your primary point of contact, working with Facilities Management.	6 months to a year
Facilities repairs, including leaks and outages	Place a work order for repairs; notify Physical Plant of emergency needs (available 24/7).	Phone Health System Physical Plant (924-2267) or request services on-line at https://www.fm.virginia.edu/requestservice.html . Request emergency response when appropriate.	
Environmental health and safety			
Transferring recombinant DNA and pathogens to UVA	Obtain approvals on both sides. Requires special shipping procedures. You cannot use such materials at UVA until you receive IBC approval (see below).	Your current biosafety committee office will offer recommendations on shipping. Your UVA administrator and the Institutional Biosafety Office will provide approval, training, and lab inspection.	Varies
Use of recombinant DNA or pathogens	Obtain required training, inspection(s) of your laboratory facilities, and committee approval(s).	Your UVA administrator will contact the Institutional Biosafety Committee to declare/register materials, obtain training, and to arrange a lab inspection.	Weeks to months (esp. if using select agents)
Use of biological, chemical, radioactive hazards	Obtain required training, inspection(s) of your laboratory facilities, and committee approval(s).	Your UVA administrator, in conjunction with the Office of Environmental Health and Safety	Weeks to months
Obtain EHS training before you arrive at UVA	Taking the on-line training now will accelerate your research program after your arrival.	Have a current UVA faculty member send an e-mail to accounts@virginia.edu containing: your full name and SSN; your department; and name of the faculty "sponsoring" your account. Request that a login ID to be created with E-Services/NetBadge access. Problems? Contact Jean Varner or Ralph Allen. Training can be accessed at http://ehs.virginia.edu/ehs/, link at right side of page.	

University of Virginia School of Medicine Standard Operating Procedure for new faculty who will perform clinical research
Latest modifications: updated links to the new Clinical Research site ver. July 2017

SOM "best practices" document on safety in the research environment	New research personnel must be given a solid grounding in safety, signage, training, etc., before initiating their work in SOM facilities.	Please refer your new hires (and anyone else working in your research areas) to this summary document.	None
Other compliance issues and training			
HIPAA privacy	Take on-line module on HIPAA privacy.	Your Department/Center administrator can arrange access to the NetLearning system.	None
Computer security	Complete UVA Information Technology and Services (ITS) on-line module. *Print and retain the final page, as evidence of completing the training.*	See ITS Web site: https://www.people.virginia.edu/quiz/itsa.rb.	None
Responsible conduct of research	Trainees on federal training grants generally take BIMS 710. Others may audit that course, but cannot participate in small-group sessions.	BIMS 7100 is Coordinated by the SOM Graduate Programs Office.	Course is held annually
Conflicts of interest (COIs)	State law and federal regulations require that conflicts associated with procurement and research be reduced, managed, or removed.	- Office for Research/Steven Wasserman - UVA Conflicts of Interest Committee/Patricia Tereskerz, Chair - SOM Conflict of Interest Committee/Donna Chen, Chair	Several weeks
Financial interest reporting	SOM conflict of interest policy requires that new faculty report their external financial interests within 30 days of appointment, and that they report any material changes in same within 30 days.	- On-line reporting system at https://coi.sites.virginia.edu - For help with that system, contact the Office for Research/Steven Wasserman	Within 30 days of appointment to SOM faculty
Effort reports	University faculty must generate semi-annual reports of their efforts.	Your UVA administrator will describe your department's methodology for keeping track of effort throughout each six-month period.	
Other training for your research staff	Provide tailored training on life safety issues for your projects (i.e. location of primary and secondary fire exits, use of protective equipment, etc.)	Work with your department administrator to ensure that all such issues are covered.	Immediately upon hiring of individual employees
Other SOM/UVA research resources			
Accessing research core facilities	Institutional or departmental facilities providing services at a reasonable cost to University users.	See the listing of institutional cores. Other cores are provided via research centers and complex research awards.	
Find UVA collaborators and consultants	Find investigators at UVA to who can strengthen your research program or provide access to equipment you can share.	Consult the Research Faculty Directory. For additional help, contact the Office for Research/Steven Wasserman.	
Register on the SOM Research Faculty Directory	Allow others to access your expertise and techniques, and to strengthen collaboration across the institution.	Contact the Graduate Programs Office to create a page in the directory.	

University of Virginia School of Medicine Standard Operating Procedure for new faculty who will perform clinical research
Latest modifications: updated links to the new Clinical Research site ver. July 2017

Computers/network/internet			
Computer purchase and set-up; network, Internet connectivity	Department desktop and network needs are supported by UVA Information Technology & Communication, Health System Computing Services, or internal personnel.	Contact your Local Support Partner (LSP) to discuss computer specifications (before ordering), set-up, and connectivity. Your administrator can point you to your LSP.	Weeks
UVA discounted/site-licensed software	Download or purchase software for use in UVA-related projects, under University site licenses.	Software: Information Technology and Communication (http://its.virginia.edu/central/). Computers and software: Cavalier Computers (www.cavcomp.virginia.edu/)	
Policies for your research group			
Authorship and data integrity policies	Create policies for your research group on authorship and data integrity.	See the School of Medicine Research web site	
Ensure proper management and integrity of research data	Read "Making the Right Moves," Chapter 8 (http://www.hhmi.org/sites/default/files/Educational%20Materials/Lab%20Management/Making%20the%20Right%20Moves/moves2.pdf), covering data recording, witnessing, retention, and security.	For additional help, contact Steven Wasserman for recommendations on data security, data-maintenance requirements for intellectual property, etc.	n/a
Security, losses			
Planning for disasters	Create a call list and laboratory policy on disasters (fire, power outages, floods)	Post your call list in your research area and provide a copy to your UVA administrator and members of your research group. Make sure that your group and administrator are aware of members who are out of town.	
Property loss/injury	Report property damage/loss or bodily injury for potential reimbursement.	Your UVA administrator can help you file a claim with Risk Management (claim form).	
Security issues	Contact HS Security or UVA Police to report a crime or to request a security assessment of your lab.	In an emergency, phone 911. For non-emergency issues: ▪ HS security: 924-5048 ▪ UVA police: 924-7166	
Emergency notification	Sign up for UV alerts: a means by which UVA employees can receive text message alerts about potential, developing, or existing emergencies.	Sign up at https://www.virginia.edu/uvaalerts/. Requires that you have a valid UVA log-in account.	