

Department of Health and Human Services

Part 1. Overview Information

Participating Organization(s)	National Institutes of Health (NIH)
Components of Participating Organizations	National Heart, Lung, and Blood Institute (NHLBI)
Funding Opportunity Title	Utilization of a Human Lung Tissue Resource for Vascular Research (R03)
Activity Code	R03 Small Grant Program
Announcement Type	New
Related Notices	<ul style="list-style-type: none"> • August 9, 2011 - Frequently Asked Questions (FAQs) for RFA-HL-11-032. See Notice NOT-HL-11-158. • October 20, 2010 - Notice of Corrections to RFA-HL-11-032 in Section IV. Application and Submission Information and Section V. Application Review Information. See NOT-HL-11-131.
Funding Opportunity Announcement (FOA) Number	RFA-HL-11-032
Companion FOA	NA
Number of Applications	See Section III. 3. Additional Information on Eligibility .
Catalog of Federal Domestic Assistance (CFDA) Number(s)	93.838
FOA Purpose	This funding opportunity announcement (FOA) solicits research grant applications from organizations that propose to conduct human tissue- and cell-based vascular research. The primary goal of this initiative is to promote research that will advance translational efforts in lung vascular disease. This program makes available human biospecimens collected by the Pulmonary Hypertension Breakthrough Initiative (PHBI). Biospecimens may be used to investigate mechanistic research questions in lung vascular biology, including validating hypotheses of pulmonary arterial hypertension (PAH) pathogenesis. Innovative use of biospecimens for addressing general vascular biology research questions is encouraged.

Key Dates

Posted Date	October 12, 2010
Open Date (Earliest Submission Date)	December 14, 2010
Letter of Intent Due Date	December 14, 2010
Application Due Date(s)	January 14, 2011; October 14, 2011, by 5:00 PM local time of applicant organization.

AIDS Application Due Date(s)	Standard dates apply or Month Day, Year, by 5:00 PM local time of applicant organization.
Scientific Merit Review	June-July 2011; March-April 2012
Advisory Council Review	August 2011; May 2012
Earliest Start Date(s)	September 30, 2011; July 1, 2012
Expiration Date	October 15, 2011
Due Dates for E.O. 12372	Not Applicable

Required Application Instructions

It is critical that applicants follow the instructions in the [SF 424 \(R&R\) Application Guide](#) except where instructed to do otherwise (in this FOA or in a Notice from the *NIH Guide for Grants and Contracts*). Conformance to all requirements (both in the Application Guide and the FOA) is required and strictly enforced. Applicants must read and follow all application instructions in the Application Guide as well as any program-specific instructions noted in [Section IV](#). When the program-specific instructions deviate from those in the Application Guide, follow the program-specific instructions. **Applications that do not comply with these instructions may be delayed or not accepted for review.**

Apply for Grant Electronically

A compatible version of [Adobe Reader](#) is required for download. For Assistance downloading this or any Grants.gov application package, please contact Grants.gov Customer Support at <http://www07.grants.gov/contactus/contactus.jsp>.

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Part 2. Full Text of Announcement

Section I. Funding Opportunity Description

1. Research Objectives

The primary goal of this initiative is to promote research that will advance translational efforts in lung vascular disease. Program objectives include supporting research that begins to validate

emerging hypotheses specific to Group 1 PAH pathogenesis and/or proposes innovative uses of PAH biospecimens to address vascular biology research questions. Attaining sufficient human lung tissue samples to perform translational studies in lung vascular disease has been difficult. Open-lung biopsy is prohibitive with respect to its morbidity, and post-mortem tissue acquisition cannot be accomplished in a timely manner. Consequently, lungs explanted from transplant patients with PAH, a vasculopathic disease, provide the only real opportunity to directly identify cellular and molecular pathways needed to accelerate translation of basic discovery into disease-modifying therapeutics for human lung vascular diseases.

This FOA fosters collaboration with the PHBI (<http://www.ipahresearch.org/>). The PHBI is a cooperative tissue harvesting network established in 2006 for the purpose of advancing understanding of idiopathic PAH. The PHBI collects blood, clinical data, and whole lungs derived from subjects ultimately undergoing lung transplantation for PAH, as well as non-used donor lungs. The PHBI network processes the whole lungs in a standardized, high-quality manner into specimens for use in histological, cellular, and sub-cellular research.

This solicitation will provide small grant support to investigators who propose meritorious studies utilizing PHBI resources or alternate sources of human lung tissues. It is anticipated that these R03 awards will provide sufficient funds for pilot studies leading to proof-of-concept testing in humans, suggested by previous findings in vitro, in animals, or in biomarker studies. Successful applicants will be encouraged to plan for subsequent grant applications (e.g., investigator-initiated R21 and/or R01 research project grant applications) using the results obtained through this small grants program. Early stage investigators are strongly encouraged to apply.

Examples of research areas appropriate to this announcement include, but are not limited to:

Identify and characterize epigenetic modifications in lung vascular-derived endothelial cells/smooth muscle cells/fibroblasts.

Identify cellular and histological features of diseased human lung vasculature that are consistent with animal models of disease.

Compare growth and cellular metabolic characteristics of endothelial cells/smooth muscle cells/fibroblasts between diseased lung vasculature and non-diseased.

Characterize mitochondrial and other organelle dysfunction in endothelial cells/smooth muscle cells/fibroblasts in Group 1 PAH.

Correlate expression of specific genes with the presence and/or severity of vascular disease.

Characterize neovascularization and growth factor expression in human PAH.

Localize inflammatory cells with focal vascular changes.

Section II. Award Information

Funding Instrument	Grant
Application Types Allowed	New, resubmission The OER Glossary and the SF 424 (R&R) Application Guide provide details on these application types.
Funds Available and Anticipated Number of Awards	NHLBI intends to commit the following amounts: NHLBI/DLD, \$1,500,000 for 10 awards in FY2011 NHLBI/DLD, \$1,500,000 for 10 awards in FY2012
Award Budget	Application budgets are not limited, but need to reflect actual needs of proposed project.
Award Project Period	Scope of the proposed project should determine the project period. The maximum period is 2 years.

NIH grants policies as described in the [NIH Grants Policy Statement](#) will apply to the applications submitted and awards made in response to this FOA.

Section III. Eligibility Information

1. Eligible Applicants

Eligible Organizations

Higher Education Institutions:

- Public/State Controlled Institutions of Higher Education
- Private Institutions of Higher Education

The following types of Higher Education Institutions are always encouraged to apply for NIH support as Public or Private Institutions of Higher Education:

- Hispanic-serving Institutions
- Historically Black Colleges and Universities (HBCUs)
- Tribally Controlled Colleges and Universities (TCCUs)
- Alaska Native and Native Hawaiian Serving Institutions

Nonprofits Other Than Institutions of Higher Education

- Nonprofits with 501(c)(3) IRS Status (Other than Institutions of Higher Education)
- Nonprofits without 501(c)(3) IRS Status (Other than Institutions of Higher Education)

For profit Organizations

- Small Businesses
- For-Profit Organizations (Other than Small Businesses)

Governments

- State Governments
- County Governments
- City or Township Governments
- Special District Governments
- Indian/Native American Tribal Governments (Federally Recognized)
- Indian/Native American Tribal Governments (Other than Federally Recognized)
- Eligible Agencies of the Federal Government
- U.S. Territory or Possession

Other

- Independent School Districts
- Public Housing Authorities/Indian Housing Authorities
- Native American tribal organizations (other than Federally recognized tribal governments)
- Faith-based or Community-based Organizations
- Regional Organizations

Non-domestic (non-U.S.) Entities (Foreign Organizations) are not eligible to apply. Foreign (non-U.S.) components of U.S. Organizations are not allowed.

Required Registrations

Applicant organizations must complete the following registrations as described in the SF 424 (R&R) Application Guide to be eligible to apply for or receive an award. Applicants must have a valid Dun and Bradstreet Universal Numbering System (DUNS) number in order to begin each of the following registrations.

- [Central Contractor Registration \(CCR\)](#) – must be renewed at least annually
- [Grants.gov](#)
- [eRA Commons](#)

All Program Directors/Principal Investigators (PD/PIs) must also work with their institutional officials to register with the eRA Commons or ensure their existing eRA Commons account is affiliated with the eRA Commons account of the applicant organization.

All registrations must be completed by the application due date. Applicant organizations are strongly encouraged to start the registration process at least four (4) weeks prior to the application due date.

Eligible Individuals (Project Director/Principal Investigator)

Any individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research as the Project Director/Principal Investigator (PD/PI) is invited to work with his/her

organization to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH support.

For institutions/organizations proposing multiple PDs/PIs, visit the Multiple Program Director/Principal Investigator Policy and submission details in the Senior/Key Person Profile (Expanded) Component of the SF 424 (R&R) Application Guide.

2. Cost Sharing

This FOA does not require cost sharing as defined in the [NIH Grants Policy Statement](#).

3. Additional Information on Eligibility

Number of Applications

Applicant organizations may submit more than one application, provided that each application is scientifically distinct.

NIH will not accept any application in response to this FOA that is essentially the same as one currently pending initial peer review unless the applicant withdraws the pending application. NIH will not accept any application that is essentially the same as one already reviewed. Resubmission applications may be submitted, according to the NIH Policy on Resubmission Applications from the SF 424 (R&R) Application Guide.

Section IV. Application and Submission Information

1. Requesting an Application Package

Applicants must download the SF424 (R&R) application package associated with this funding opportunity using the “Apply for Grant Electronically” button in this FOA or following the directions provided at [Grants.gov](#).

2. Content and Form of Application Submission

It is critical that applicants follow the instructions in the [SF424 \(R&R\) Application Guide](#), except where instructed in this funding opportunity announcement to do otherwise. Conformance to the requirements in the Application Guide is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review.

Letter of Intent

Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows IC staff to estimate the potential review workload and plan the review.

By the date listed in [Part 1. Overview Information](#), prospective applicants are asked to submit a letter of intent that includes the following information:

Descriptive title of proposed research
Name, address, and telephone number of the PD(s)/PI(s)
Names of other key personnel
Participating institutions
Number and title of this funding opportunity

The letter of intent should be sent to:

Director, Office of Scientific Review
National Heart, Lung, and Blood Institute
National Institutes of Health
6701 Rockledge Drive, Room 7214, MSC 7214
Bethesda, MD 20892-7214
Bethesda, MD 20817 (express/courier service)
Telephone: 301-435-0270
Fax: (301) 480-0730
Email: nhlbchiefreviewbranch@nhlbi.nih.gov

Required and Optional Components

The forms package associated with this FOA includes all applicable components, mandatory and optional. Please note that some components marked optional in the application package are required for application submission. Follow all instructions in the SF424 (R&R) Application Guide to ensure you complete all appropriate “optional” components.

Page Limitations

All page limitations described in the SF424 Application Guide and the [Table of Page Limits](#) must be followed.

Resource Sharing Plans

Individuals are required to comply with the instructions for the Resource Sharing Plans (Data Sharing Plan, Model Organisms Sharing Plan, and Genome Wide Association Studies (GWAS) Sharing Plan) as provided in the SF424 (R&R) Application Guide).

PHS 398 Research Plan Component

All instructions in the SF424 (R&R) Application Guide must be followed.

Appendix

Do not use the appendix to circumvent page limits. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide, with the following modifications:

- No publications or other printed material, with the exception of pre-printed questionnaires or surveys, may be included in the Appendix.

3. Submission Dates and Times

[Part I. Overview Information](#) contains information about Key Dates. Applicants are encouraged to submit in advance of the deadline to ensure they have time to make any application corrections that might be necessary for successful submission.

Organizations must submit applications via [Grants.gov](#), the online portal to find and apply for grants across all Federal agencies. Applicants must then complete the submission process by tracking the status of the application in the [eRA Commons](#), NIH's electronic system for grants administration.

Applicants are responsible for viewing their application in the eRA Commons to ensure accurate and successful submission.

Information on the submission process and a definition of on-time submission are provided in the SF424 (R&R) Application Guide.

4. Intergovernmental Review (E.O. 12372)

This initiative is not subject to [intergovernmental review](#).

5. Funding Restrictions

All NIH awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement.

Pre-award costs are allowable only as described in the [NIH Grants Policy Statement](#).

6. Other Submission Requirements and Information

Applications must be submitted electronically following the instructions described in the SF 424 (R&R) Application Guide. Paper applications will not be accepted.

Applicants must complete all required registrations before the application due date. [Section III. Eligibility Information](#) contains information about registration.

For assistance with your electronic application or for more information on the electronic submission process, visit [Applying Electronically](#).

Important reminders:

All PD/PIs must include their eRA Commons ID in the Credential field of the Senior/Key Person Profile Component of the SF 424(R&R) Application Package. Failure to register in the Commons and to include a valid PD/PI Commons ID in the credential field will prevent the

successful submission of an electronic application to NIH.

The applicant organization must ensure that the DUNS number it provides on the application is the same number used in the organization's profile in the eRA Commons and for the Central Contractor Registration (CCR). Additional information may be found in the SF424 (R&R) Application Guide.

See [more tips](#) for avoiding common errors.

Upon receipt, applications will be evaluated for completeness by the Center for Scientific Review and responsiveness by [NHLBII](#), NIH. Applications that are incomplete and/or nonresponsive will not be reviewed.

Post Submission Materials

Applicants are required to follow the instructions for post-submission materials, as described in [NOT-OD-10-115](#),

Section V. Application Review Information

1. Criteria

The R03 small grant supports discrete, well-defined projects that realistically can be completed in two years and that require limited levels of funding. Because the research project usually is limited, an R03 grant application may not contain extensive detail or discussion. Accordingly, reviewers should evaluate the conceptual framework and general approach to the problem. Appropriate justification for the proposed work can be provided through literature citations, data from other sources, or from investigator-generated data. Preliminary data are not required, particularly in applications proposing pilot or feasibility studies.

Overall Impact

Reviewers will provide an overall impact/priority score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following review criteria and additional review criteria (as applicable for the project proposed).

Scored Review Criteria

Reviewers will consider each of the review criteria below in the determination of scientific merit, and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

Significance

Does the project address an important problem or a critical barrier to progress in the field? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

Investigator(s)

Are the PD/PIs, collaborators, and other researchers well suited to the project? If Early Stage Investigators or New Investigators, or in the early stages of independent careers, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?

Innovation

Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

Approach

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed?

If the project involves clinical research, are the plans for 1) protection of human subjects from research risks, and 2) inclusion of minorities and members of both sexes/genders, as well as the inclusion of children, justified in terms of the scientific goals and research strategy proposed?

Environment

Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

Additional Review Criteria

As applicable for the project proposed, reviewers will evaluate the following additional items while determining scientific and technical merit, and in providing an overall impact/priority score, but will not give separate scores for these items.

Protections for Human Subjects

For research that involves human subjects but does not involve one of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials.

For research that involves human subjects and meets the criteria for one or more of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials. For additional information on review of the Human Subjects section, please refer to the [Human Subjects Protection and Inclusion Guidelines](#).

Inclusion of Women, Minorities, and Children

When the proposed project involves clinical research, the committee will evaluate the proposed plans for inclusion of minorities and members of both genders, as well as the inclusion of children. For additional information on review of the Inclusion section, please refer to the [Human Subjects Protection and Inclusion Guidelines](#).

Vertebrate Animals

The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following five points: 1) proposed use of the animals, and species, strains, ages, sex, and numbers to be used; 2) justifications for the use of animals and for the appropriateness of the species and numbers proposed; 3) adequacy of veterinary care; 4) procedures for limiting discomfort, distress, pain and injury to that which is unavoidable in the conduct of scientifically sound research including the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices; and 5) methods of euthanasia and reason for selection if not consistent with the AVMA Guidelines on Euthanasia. For additional information on review of the Vertebrate Animals section, please refer to the [Worksheet for Review of the Vertebrate Animal Section](#).

Biohazards

Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.

Resubmissions

For Resubmissions, the committee will evaluate the application as now presented, taking into consideration the responses to comments from the previous scientific review group and changes made to the project.

Renewals

Renewals are not allowed in this FOA.

Revisions

Revisions are not allowed for this FOA.

Additional Review Considerations

As applicable for the project proposed, reviewers will consider each of the following items, but will not give scores for these items, and should not consider them in providing an overall impact/priority score.

Applications from Foreign Organizations

N/A

Select Agent Research

Reviewers will assess the information provided in this section of the application, including 1) the Select Agent(s) to be used in the proposed research, 2) the registration status of all entities where Select Agent(s) will be used, 3) the procedures that will be used to monitor possession use and transfer of Select Agent(s), and 4) plans for appropriate biosafety, biocontainment, and security of the Select Agent(s).

Resource Sharing Plans

Reviewers will comment on whether the following Resource Sharing Plans, or the rationale for not sharing the following types of resources, are reasonable: 1) [Data Sharing Plan](#); 2) [Sharing Model Organisms](#); and 3) [Genome Wide Association Studies \(GWAS\)](#).

Budget and Period of Support

Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research.

2. Review and Selection Process

Applications will be evaluated for scientific and technical merit by (an) appropriate Scientific Review Group(s) convened by the NHLBI (assignments will be shown in the eRA Commons), in accordance with [NIH peer review policy and procedures](#), using the stated [review criteria](#).

As part of the scientific peer review, all applications will:

- Receive a written critique.

Applications will be assigned to the appropriate NIH Institute or Center. Applications will compete for available funds with all other recommended applications submitted in response to this FOA . Following initial peer review, recommended applications will receive a second level of review by the NHLBI Advisory Council . The following will be considered in making funding decisions:

- Scientific and technical merit of the proposed project as determined by scientific peer review.
- Availability of funds.
- Relevance of the proposed project to program priorities.

3. Anticipated Announcement and Award Dates

After the peer review of the application is completed, the PD/PI will be able to access his or her Summary Statement (written critique) via the [eRA Commons](#).

Information regarding the disposition of applications is available in the [NIH Grants Policy Statement](#).

Section VI. Award Administration Information

1. Award Notices

If the application is under consideration for funding, NIH will request "just-in-time" information from the applicant as described in the [NIH Grants Policy Statement](#).

A formal notification in the form of a Notice of Award (NoA) will be provided to the applicant organization for successful applications. The NoA signed by the grants management officer is the authorizing document and will be sent via email to the grantee business official.

Awardees must comply with any funding restrictions described in [Section IV.5. Funding Restrictions](#). Selection of an application for award is not an authorization to begin performance. Any costs incurred before receipt of the NoA are at the recipient's risk. These costs may be reimbursed only to the extent considered allowable pre-award costs.

2. Administrative and National Policy Requirements

All NIH grant and cooperative agreement awards include the *NIH Grants Policy Statement* as part of the NoA. For these terms of award, see the [NIH Grants Policy Statement Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General](#) and [Part II: Terms and Conditions of NIH Grant Awards, Subpart B: Terms and Conditions for Specific Types of Grants, Grantees, and Activities](#). More information is provided at [Award Conditions and Information for NIH Grants](#).

3. Reporting

When multiple years are involved, awardees will be required to submit the [Non-Competing Continuation Grant Progress Report \(PHS 2590\)](#) annually and financial statements as required in the [NIH Grants Policy Statement](#).

A final progress report, invention statement, and Financial Status Report are required when an award is relinquished when a recipient changes institutions or when an award is terminated.

Section VII. Agency Contacts

We encourage inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants.

Application Submission Contacts

[Grants.gov Customer Support](#) (Questions regarding Grants.gov registration and submission, downloading or navigating forms)

Contact Center Phone: 800-518-4726

Email: support@grants.gov

GrantsInfo (Questions regarding application instructions and process, finding NIH grant resources)

Telephone 301-435-0714

TTY 301-451-5936

Email: GrantsInfo@nih.gov

eRA Commons Help Desk (Questions regarding eRA Commons registration, tracking application status, post submission issues)

Phone: 301-402-7469 or 866-504-9552 (Toll Free)

TTY: 301-451-5939

Email: commons@od.nih.gov

Scientific/Research Contact(s)

Timothy M. Moore, M.D., Ph.D.

Division of Lung Diseases

(National Heart, Lung, and Blood Institute

National Institutes of Health

6701 Rockledge Drive, Room 10182, MSC 7952

Bethesda, MD 20892-7952)

Telephone: 301-435-0222

Email: Tim.Moore@nih.gov

Peer Review Contact(s)

Director, Office of Scientific Review

Division of Extramural Research Activities

National Heart, Lung, and Blood Institute
National Institutes of Health
6701 Rockledge Drive, Room 7214, MSC 7924
Bethesda, MD 20891-7924
Bethesda, MD 20817 (express/courier service)
Telephone: (301) 435-0270
Fax: (301) 480-0730
Email: nhlbchiefreviewbranch@nhlbi.nih.gov.

Financial/Grants Management Contact(s)

David Ruane
(Office of Grants Management
Division of Extramural Affairs
National Heart, Lung, and Blood Institute
National Institutes of Health
6701 Rockledge Drive, Room 7044, MSC 7926
Bethesda, MD 20891-7926)
Telephone: 301-435-0166
Email: ruaned@nhlbi.nih.gov

Section VIII. Other Information

Recently issued trans-NIH [policy notices](#) may affect your application submission. A full list of policy notices published by NIH is provided in the [NIH Guide for Grants and Contracts](#). All awards are subject to the terms and conditions, cost principles, and other considerations described in the [NIH Grants Policy Statement](#).

Authority and Regulations

Awards are made under the authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and under Federal Regulations 42 CFR Part 52 and 45 CFR Parts 74 and 92.

[Weekly TOC for this Announcement](#)
[NIH Funding Opportunities and Notices](#)

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Note: For help accessing PDF, RTF, MS Word, Excel, PowerPoint, Audio or Video files, see [Help Downloading Files](#).