List Registering non-UMCG research

# Please fill out all questions in the form. Save the file as word-document. Add date and name in the document description (e.g 20200121\_List registering non UMCG research\_BdeBouwer). Email it to researchsupport@umcg.nl

|  |  |
| --- | --- |
| Study Title (volledige titel studie) |  |
| Study Acronym (optional) |  |
| Name Principal Investigator (PI)(eindverantwoordelijk hoofdonderzoeker) |  |
| Telephone number PI |  |
| Email address Principal Investigator |  |
| Email address of contact person of the study |  |
| Name (sub- or co-) investigator(s) |  |
| End responsibility study |  Choose an item. |
| Specify name ‘External party’ |  |
| Funding(1 explanation, see below) |  Choose an item  |
| Specify ‘other flow funds’ |  |
| Does the WMO apply | Yes / No / Not sure |
| Risk classification NFU(2 explanation, see below) |  Choose an item. |
| Will monitoring be arranged  | Yes / No / Not known yet |
| Study type |  Choose an item. |
| Specify ‘other study type’ |  |
| Multi-center or monocenter study |  |
| Type of study subjects  | Healthy volunteers, patients or both? |
| Age of the study subjects? |   |
| Are one or more subjects incapacitated? | Y/N |
| Target number of participants (in total) |  |
| Target number of participants in UMCG |  |
| Planned start date |  Click here to enter a date. |
| Estimated completion date |  Click here to enter a date. |

**1 explanation funding**

1st flow of funds: money that goes directly from the Ministry of OC&W to the universities for the funding of Education and Research.

2nd flow of funds: money from the Ministry of OC&W to be distributed among the universities on the basis of grant of research projects (open competition) via institutes (NWO / KNAW).

3rd and 4th flow of funds: all research and education funds obtained in the "free market". This could include charities, institutes, European Union (including ERC), industry, ministries and national governments, local authorities (including SNN) etc.

The distinction between the 4th and 3rd funding:

• 3rd flow of funds: non-commercial research

• 4th flow of funds: commercial research (contract research)

**2 explanation risk classification**

The risk of the studies is divided in three risk categories: Negligible (verwaarloosbaar), Moderate (matig), High (hoog). Please note that you only have to assess the additional risk of study procedures for patient safety, as compared to standard of care.

The definition of negligible, moderate, high is described by the NFU in the following table:

|  |  |  |  |
| --- | --- | --- | --- |
|  Degree of harmSize risk | Light harm | Moderate harm | Serious harm |
| Small chance | Negligible risk | Negligible risk | Moderate risk |
| Moderate chance | Negligible risk | Moderate risk | High risk |
| Large chance | Moderate risk | High risk | High risk |

For more information, see:

<https://www.nfu.nl/img/pdf/19.1360_Richtlijn_kwaliteitsborging_mensgebonden_onderzoek_2019.pdf>